**File No.: MED-16014(12)/1/2024-eoffice**
**Government of India**
**Directorate General of Health Services**
**Central Drugs Standard Control Organisation**

FDA Bhawan, Kotla Road,
New Delhi – 110002
Dated: 26 NOV 2025

**Notice**

**Subject: Risk classification list of medical devices pertaining to Interventional Radiology - Reg.**

Consequent to the publication of draft risk classification lists vide File No. MED-16014(12)/1/2024-eoffice dated 06.01.2025, and in exercise of the powers conferred under sub-rule(3) of Rule 4 of the Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices pertaining to Interventional Radiology, under the Medical Devices Rules, 2017.

The risk classification list of medical devices pertaining to Interventional Radiology is placed in the attached **Appendix A** and it is subject to the following:

1. General intended use given against each of the devices is for guidance of the applicants who intend to furnish applications for manufacturing/import of medical devices under the Medical Devices Rules, 2017. However, a device may have a specified intended use as specified by its manufacturer.
2. This list is dynamic and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

**(Dr. Rajeev Singh Raghuvanshi)**
**Drugs Controller General (I)**

**To:**

**All Stakeholders via CDSCO website**

**Appendix A**

**File No.: MED-16014(12)/1/2024-eoffice**

## Notice

## Classification of Medical Devices Pertaining to Interventional Radiology

| S. No. | Device name | Intended use | Risk Classification |
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| 1 | Angiographic x- ray system | An angiographic x-ray system is a device intended for radiologic visualization of the heart, blood vessels, or lymphatic system during or after injection of a contrast medium. | **Class C** |
| 2 | Angiography contrast medium injection system, battery-powered | A battery-powered assembly of devices intended to inject contrast media through a small catheter and into the vascular system for angiographic procedures (e.g., examination of the coronary and renal arteries, and great vessels and vasculature of the heart, brain, abdominal organs, and extremities). | **Class C** |
| 3 | Angiography contrast medium injection system, line-powered, mobile/stationary | An assembly of devices intended to inject contrast media through a small catheter and into the vascular system for angiographic procedures (e.g., examination of the coronary and renal arteries, and great vessels and vasculature of the heart, brain, abdominal organs, and extremities). It may additionally synchronize media delivery with the electrocardiographic cycle and/or the x-ray generator. | **Class C** |
| 4 | Automatic-aperture-control diagnostic x-ray system collimator | A standard, diagnostic x-ray beam-limiting and shaping device intended to limit the effects of scattered radiation on image quality and to provide patient protection by eliminating exposure to non-target body areas by automatically adjusting the shutters so that the x-ray beam shape matches the size of the film cassette in the holder. | **Class B** |
| 5 | Axial length measuring ultrasound system | An ophthalmic device intended to measure axial length of the eye (distance along the axis of the eye between the anterior corneal surface and the anterior retinal surface) using ultrasound technology. | **Class B** |
| 6 | Basic/General-purpose diagnostic x-ray system, mobile/stationary/ portable | An assembly of devices that comprise an analogue general-purpose diagnostic x-ray system used in a variety of routine x-ray imaging applications using analogue or analogue-to-digital technologies. It may be used for bedside imaging and for interventional and intraoperative imaging. | **Class C** |
| 7 | Bladder ultrasound imaging transducer | An ultrasound imaging transducer assembly specifically intended to be positioned within the bladder either manually or under endoscopic guidance that steers, focuses, and detects the ultrasound beam and resulting echoes either mechanically or electronically. | **Class B** |
| 8 | Bladder volume ultrasound imaging system | An assembly of devices intended for the extracorporeal ultrasound measurement of the male or female urinary bladder volume. It is used in the diagnosis of urinary retention and postoperative urinary retention (POUR). | **Class B** |

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| 9 | Blood flowmeter catheter, Doppler | A flexible tube intended to be inserted into the lumen of a blood vessel to determine blood-flow velocity by measuring the ultrasonic frequency shift between transmitted and reflected signals (Doppler principle). | **Class C** |
| 10 | Body-orifice ultrasound imaging transducer cover | A sheath intended to be used as a physical barrier for protection against the effects of environmental exposure (e.g., body fluids, gliding creams) and/or to maintain the required hygienic level of an ultrasound imaging system transducer (probe) used in natural body orifices (e.g., vagina, rectum, oesophagus) during an ultrasound examination; it has no additional functionality. | **Class B** |
| 11 | Body-orifice ultrasound imaging transducer cover, image-enhancement | Intended to cover an ultrasound imaging system transducer (probe) used in natural body orifices (e.g., vagina, rectum), to both protect the transducer and improve image quality. The balloon portion is intended to, when filled with an aqueous solution (e.g., saline), displace air and provide an adjustable interface between the transducer and the anatomy of interest (e.g., prostate) to improve imaging. | **Class B** |
| 12 | Bone densitometer | A bone densitometer is a device intended for medical purposes to measure bone density and mineral content by x-ray or gamma ray transmission measurements through the bone and adjacent tissues. | **Class C** |
| 13 | Bone sonometer | A bone sonometer is a device that transmits ultrasound energy into the human body to measure acoustic properties of bone that indicate overall bone health and fracture risk. | **Class B** |
| 14 | Cardiovascular MRI system, Permanent magnet | A magnetic resonance (MR) diagnostic imaging device specifically intended to visualize the cardiovascular system. The device uses a permanent magnet, and can be stationary, mobile, or portable. | **Class C** |
| 15 | Cardiovascular MRI system, resistive magnet | A magnetic resonance (MR) diagnostic imaging device specifically intended to visualize the cardiovascular system. The device uses a resistive magnet. | **Class C** |
| 16 | Cardiovascular MRI system, Superconducting magnet | A magnetic resonance (MR) diagnostic imaging device specifically intended to visualize the cardiovascular system. The device uses a superconducting magnet, and can be stationary, mobile, or portable. | **Class C** |
| 17 | Cardiovascular ultrasound imaging system | An assembly of devices intended for imaging procedures involving the heart and blood vessels. Software packages that support a static or real-time cardiac specific imaging applications for diagnosing anatomical defects of the heart, determine blood flow characteristics and functional/anatomical problems associated with myocardial infarction, may be included. This does not include intracardiac or intracoronary catheters/probes. | **Class C** |
| 18 | Cephalometric digital X-ray sensor | A sensor for a digital X-ray image processing system combined with a diagnostic X-ray system intended for visualization and size measurement of the human head (skull) using radiation. | **Class C** |

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| 19 | Cine or spot fluorographic x-ray camera | A cine or spot fluorographic x-ray camera is a device intended to photograph diagnostic images produced by x-rays with an image intensifier. | **Class C** |
| 20 | Computed radiography digital imaging scanner | A device/device assembly intended to be used with an analogue x-ray system (not included) to capture radiographic images and then generate digital x-ray images from them as part of a two-step process (computed radiography) for image viewing, storage, or hard-copy printing; it is not dedicated to dental use. | **Class B** |
| 21 | Computer system for ultrasound imaging system | A mainframe computer, a personal computer (PC) or a PC-based platform, and related hardware, software and operating system software dedicated used for controlling and monitoring performance of a diagnostic ultrasound system and related image processing, display and analytical functions. | **Class B** |
| 22 | Contrast medium conservation system (Contrast management system) | An assembly of electromechanical devices intended to control and optimize the amount of injectible contrast agent supplied to the syringe/injector portion of the contrast medium injector system, in order to prevent unnecessary waste of contrast media during and/or between patient procedures. | **Class B** |
| 23 | Contrast medium injection system administration set | A collection of noninvasive devices intended to conduct fluids between a contrast medium injection system and a patient catheter for the delivery of a contrast medium and/or saline solution to a patient undergoing a diagnostic imaging procedure. It may consist of tubing with switches/valves and connectors to syringes/fluid/contrast medium injection system, and possibly a pressure transducer. This is a disposable device. | **Class B** |
| 24 | Contrast medium injection system control unit | An electronic device that may be a component of a contrast medium injector system and intended to initiate and terminate the operation of a contrast medium injection procedure from a remote location (e.g., the shielded operators control room). | **Class C** |
| 25 | Contrast medium injection system hand controller kit | A collection of non-powered devices intended to interact with a contrast medium injection system for the administration of a contrast medium or saline solution to a patient undergoing a diagnostic imaging procedure. It consists of a high pressure line, a high pressure stopcock, and a hand-held manual controller used to stop and start the contrast medium injection system instantaneously. | **Class C** |
| 26 | Contrast medium injection system syringe | A component of a contrast medium injection system for the administration of a contrast medium or saline solution to a patient undergoing a diagnostic imaging procedure. | **Class B** |
| 27 | Coronary optical coherence tomography system | An assembly of optical and computer-based devices intended for optical coherence tomography (OCT) to provide high-resolution images (e.g., 5 to 40 microns) of the coronary intravasculature. The system may be used during interventional cardiology, radiology, or diagnostic angiography. The system does not include an intracoronary catheter/probe. | **Class C** |

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| 28 | Coronary optical coherence tomography system catheter | A sterile flexible tube with an extremely fine working end that houses an optical fibre and imaging lens intended to be transcutaneously introduced into the coronary vasculature to perform coronary optical coherence tomography (OCT). | **Class D** |
| 29 | CT contrast medium injection system, stationary/mobile | An assembly of devices intended to inject contrast media through a small catheter and into the vascular system for computed tomography (CT) procedures (e.g., spine, head, gastrointestinal, or vascular diagnostic procedures using CT scanning). The system may synchronize media delivery with the x-ray generator during CT scanning. | **Class C** |
| 30 | Dental computed radiography digital imaging scanner | A device/device assembly dedicated to dental use and intended to be used with an analogue dental x-ray system to capture radiographic images and then generate digital x-ray images from them as part of a two-step process (computed radiography) for image viewing, storage, or hard-copy printing. | **Class B** |
| 31 | Dental digital X-ray imaging sensor | A digital dental X-ray sensor used in the oral cavity, in combination with a general- purpose dental X-ray imaging device. The sensor consists of a CCD or other components, and comprises a sensor drive circuit and a signal processing circuit. | **Class B** |
| 32 | Dental x-ray film, screen | A screen x-ray film specifically sized and intended for use with dental x-ray systems. It is designed to be sensitive primarily to the wavelengths of light emitted from an image intensifying screen. May be used endorally/extraorally. | **Class B** |
| 33 | Diagnostic ultrasonic transducer | A diagnostic ultrasonic transducer is intended for use in diagnostic ultrasonic medical devices for the conversion of electrical signals into acoustic signals and vice versa. | **Class B** |
| 34 | Diagnostic x-ray beam-limiting device | A diagnostic x-ray beam-limiting device is a device such as a collimator, a cone, or an aperture intended to restrict the dimensions of a diagnostic x-ray field by limiting the size of the primary x-ray beam. | **Class B** |
| 35 | Diagnostic x-ray digital imaging conversion system | An assembly of medical devices intended to convert an existing analogue x-ray system to digital (i.e., retrofit) through the acquisition and processing of digital images using existing analogue x-ray system components. It may consist of: 1) a filmless cassette-size digital detector (e.g., indirect flat panel detector); and/or 2) additional processing/viewing hardware [e.g., a central processing unit (CPU) with integrated software and a monitor]. It does not contain the controls for the direct operation of an x-ray imaging system. | **Class B** |
| 36 | Diagnostic x-ray digital imaging system workstation | A freestanding component of an x-ray-based diagnostic digital imaging assembly intended to associate X-ray/CT/fluoroscopic images with patient and exam information, apply images processing to facilitate diagnosis, display the images, and output the resulting image and exam data for further display, distribution, or archiving. It does not have controls for direct operation of the imaging system. | **Class B** |

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| 37 | Diagnostic x-ray high voltage generator | A diagnostic x-ray high voltage generator is a device that is intended to supply and control the voltage and electrical energy provided to a diagnostic x-ray tube for medical purposes. | **Class B** |
| 38 | Diagnostic x-ray tube housing assembly | A metallic (e.g., steel, aluminium alloy) case that houses an x-ray tube to provide appropriate limits for x-ray leakage and adequate insulation to avoid electric risks during a diagnostic x-ray procedure. It includes lead shielding to shield unwanted x-ray radiation. It may or may not include collimators near the aperture; it is usually filled with oil to prevent electrical arcs from the high-voltage components of the x-ray tube. The housing may also include attachment points, cooling means, high-voltage cables, supports for the tube and cable receptacles. | **Class B** |
| 39 | Digital angiographic x-ray system, mobile/stationary/portable | An assembly of devices intended to visualize and optimize the macroscopic or quantitative evaluation of the anatomy and function of the blood and lymphatic systems in the heart, brain, or other organs. | **Class C** |
| 40 | Digital basic diagnostic x-ray system, mobile/portable/stationary | An assembly of devices intended for use in a variety of routine planar x-ray imaging applications. It uses digital techniques for image capture, display and manipulation. It is commonly used for bedside imaging and for interventional and intraoperative imaging. | **Class C** |
| 41 | Digital cephalometric x-ray system | An x-ray system intended to generate and control x-ray beams and to record the absorption patterns of x-rays passing through a patient's head (skull). It may be used for: 1) radiographic visualization and measurement of the dimensions of the human head, e.g., abnormal structures of the skull; 2) orthodontic assessment of the relationship of the teeth to the jaws and the jaws to the rest of the facial skeleton; 3) assessment airway and other soft tissue structures. | **Class C** |
| 42 | Digital general-purpose fluoroscopic x-ray system, mobile/portable/stationary | A general-purpose diagnostic fluoroscopic x-ray system that uses a C-arm and digital techniques for image capture, display and manipulation and is intended to be used in a variety of general-purpose applications requiring real-time fluoroscopic imaging capabilities. It is also intended to optimize the capability of users to visually and quantitatively evaluate the anatomy and physiological function of various targeted body areas in real-time. | **Class C** |
| 43 | Digital imaging cassette/storage phosphor screen, basic diagnostic x-ray (CR cassette) | A device that includes both a digital imaging cassette and a phosphor plate (also known as screen) intended to receive radiation by a diagnostic x-ray system, to record a patient radiation pattern during a non-dental procedure. The device is then transferred, with the cassette shielding the plate from environmental light, to a computed radiography (CR) scanner for insertion to produce the digital image of the patient. | **Class B** |
| 44 | Digital intraoral dental x-ray system, mobile/portable/stationary /hand-held | A diagnostic dental x-ray system intended to generate and control x-ray beams for general-purpose, routine, dental radiography examinations involving the diagnosis and treatment (e.g., surgical or interventional) of diseases of the teeth, jaw and oral cavity structures. The data is either from analogue-to-digital conversion techniques imaging or by digital imaging. | **Class C** |

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| 45 | Digital mammographic x-ray system, mobile/stationary/portable | An assembly of devices specifically intended to image the breast for diagnostic purposes using x-rays. It may be used for breast cancer screening and in conjunction with biopsy markers and stereotactic biopsy and lesion localization equipment requiring x-ray guidance. | **Class C** |
| 46 | Digital panoramic/tomographic dental x-ray system (OPG) | A diagnostic digital dental x-ray system intended to generate and control x-ray beams used in advanced dental imaging applications involving the teeth, jaw, oral cavity, sinus, and/or other maxillofacial structures. | **Class C** |
| 47 | Digital uro-gynaecological fluoroscopic x-ray system | A diagnostic x-ray system with real-time fluoroscopic capabilities specifically intended for use in urological and/or gynaecological surgical and interventional procedures requiring real-time visualization of the pelvic area. | **Class C** |
| 48 | Doppler blood-flow measurement ultrasound system | A portable or stationary ultrasonic device that does not produce 2-dimensional or 3-dimensional images, and is intended to be used for determining various blood-flow related parameters. | **Class B** |
| 49 | Electrostatic x- ray imaging system | An electrostatic x-ray imaging system is a device intended for medical purposes that uses an electrostatic field across a semiconductive plate, a gas-filled chamber, or other similar device to convert a pattern of x- radiation into an electrostatic image and, subsequently, into a visible image. | **Class C** |
| 50 | Emission computed tomography system | An emission computed tomography system is a device intended to detect the location and distribution of gamma ray- and positron-emitting radionuclides in the body and produce cross-sectional images through computer reconstruction of the data. | **Class C** |
| 51 | Extracorporeal ultrasound imaging transducer, hand-held (ultrasound probe) | A hand-held noninvasive component of an ultrasound imaging assembly intended to be moved over the intact surface of a patient's body, typically with a coupling gel, during a variety of extracorporeal ultrasound imaging procedures (non-dedicated). | **Class B** |
| 52 | Extremity MRI system, permanent magnet | A diagnostic magnetic resonance imaging (MRI) system employing permanent magnet technology specifically intended to image only the head and neck or limbs. | **Class B** |
| 53 | Extremity MRI system, superconducting magnet | A diagnostic magnetic resonance imaging (MRI) system employing superconducting magnet technology specifically intended to image only the head and neck or limbs. | **Class B** |
| 54 | Flat panel radiography and fluoroscopy system | A digital image acquisition system in which X-rays passed through a human body are captured by an X-ray flat panel detector, and digital output signals are supplied to an image processing device to receive digital images. | **Class C** |
| 55 | Flexible endoscopic ultrasound imaging transducer | A flexible, ultrasound imaging transducer assembly intended to be inserted through the working channel of an appropriate flexible endoscope and positioned within the gastrointestinal, respiratory or urinary tract, (i.e., application is not specific to any particular anatomy) to transmit a signal/data to another device for display. This is a reusable device. | **Class B** |

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| 56 | Flexible ultrasound bronchoscope | An endoscope with a flexible inserted portion intended for the visual examination and treatment of the trachea, bronchi, and lungs. It is inserted through the mouth or nose during bronchoscopy. | **Class B** |
| 57 | Flexible ultrasound colonoscope | An endoscope with a flexible inserted portion intended for the visual examination and treatment of the entire colon [lower gastrointestinal (GI) tract]. It is inserted through the anus during colonoscopy. | **Class B** |
| 58 | Flexible ultrasound duodenoscope | An endoscope with a flexible inserted portion, combined with an ultrasound probe, intended for the visual examination and treatment of the duodenum (the first part of the small intestine). It is inserted into the body through the mouth during duodenoscopy. | **Class B** |
| 59 | Flexible ultrasound gastroduodenoscope | An endoscope with a flexible inserted portion, combined with an ultrasound probe, intended for the visual examination and treatment of the upper gastrointestinal (GI) tract [oesophagus, stomach, and duodenum (the first part of the small intestine), including the pancreas and the bile duct]. It is inserted into the body through the mouth during gastroduodenoscopy. | **Class B** |
| 60 | Flexible ultrasound laparoscope | An endoscope with a flexible inserted portion, combined with an ultrasound probe, intended for the visual examination, treatment, and ultrasonic imaging of the abdominal/retroperitoneal cavity and its organs. It is inserted through an incision made in the abdominal wall (routinely just below the umbilicus) during laparoscopy. | **Class B** |
| 61 | Fluorescent scanner | A fluorescent scanner is a device intended to measure the induced fluorescent radiation in the body by exposing the body to certain x-rays or low-energy gamma rays. | **Class C** |
| 62 | Foetal cardiac monitor | A mains electricity (AC-powered) device intended to detect, measure, and display foetal heart activity during the perinatal period. | **Class C** |
| 63 | Foetal Doppler system | An assembly consisting of a measuring and display unit and an attached probe or interchangeable probes intended to noninvasively detect foetal heart beats using ultrasound/Doppler technology. The device aids in determining foetal viability. | **Class C** |
| 64 | Full-body MRI system, permanent magnet | A general-purpose magnetic resonance imaging (MRI) system intended to scan any targeted area of the body for diagnostic imaging purposes. It includes a permanent magnet assembly. | **Class C** |
| 65 | Full-body MRI system, resistive magnet | A diagnostic general-purpose magnetic resonance imaging (MRI) system intended to scan any targeted area of the body (full-body imaging) for diagnostic purposes. It includes a resistive magnet assembly. | **Class C** |
| 66 | Full-body MRI system, superconducting magnet | A diagnostic general-purpose magnetic resonance imaging (MRI) system designed to scan any targeted area of the body (full-body imaging). This system includes a superconducting magnet assembly. | **Class C** |

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| 67 | General- purpose ultrasound imaging system | A stationary or mobile assembly of devices intended to collect, display, and analyse ultrasound images during a variety of ultrasound imaging procedures (e.g., OB/GYN, endoscopy, breast, prostate, etc). It does not include intracardiac/intracoronary/intracranial probes/catheters. | **Class B** |
| 68 | General-purpose fluoroscopic x-ray system, mobile/portable/ stationary | A general-purpose, analog diagnostic fluoroscopic x-ray system intended to be used in a variety of general-purpose applications requiring real-time fluoroscopic imaging capabilities. | **Class C** |
| 69 | Grid for MRI (needle guide positioner) | A non-powered device intended to position the puncture site etc., when biopsying under the magnetic resonance imaging (MRI) guide. | **Class A** |
| 70 | Hand-held intraoral dental x-ray system | A hand-held, diagnostic dental x-ray system intended to generate and control x-ray beams used for general-purpose, routine, dental radiography examinations involving the diagnosis and treatment (e.g., surgical or interventional) of diseases of the teeth, jaw and oral cavity structures. | **Class C** |
| 71 | Hand-held ultrasound imaging system, body-surface | A battery-powered, hand-held device/device assembly intended to be placed over the external body surface for collection, display, and analysis of ultrasound information during a variety of ultrasound imaging procedures (i.e., non-dedicated); it may in addition be intended to be used with a sterile cover for intraoperative imaging. It is not designed to be inserted into body orifices. | **Class B** |
| 72 | Hand-held ultrasound imaging system, rectal/vaginal | A battery-powered, hand-held device/device assembly intended to be inserted in vaginal/rectal cavity for collection, display, and analysis of ultrasound information during a variety of ultrasound imaging procedures (i.e., non-dedicated); it may in addition be intended to be used with a sterile cover for intraoperative imaging. | **Class B** |
| 73 | Hand-held-detector nuclear medicine system | An assembly of diagnostic devices comprising a hand-held, non-imaging system intended primarily to detect, record, quantify and analyse various radioactive emissions (gamma, alpha, beta) of injected or ingested radiopharmaceuticals, radiation emitting devices, or other materials. | **Class B** |
| 74 | Head/extremity imaging MRI system | A magnetic resonance (MR) diagnostic imaging device specifically intended to visualize the head, neck, or limbs. | **Class C** |
| 75 | Hepatic ultrasound elastography system | An assembly of devices intended to measure liver stiffness/ultrasonic attenuation of tissues based on transient elastography for the evaluation/diagnosis of hepatic disease (e.g., liver fibrosis/steatosis); it may additionally be intended to measure spleen stiffness as an adjunct evaluation. It is typically used during diagnosis of chronic liver conditions such as viral hepatits, alcoholic hepatitis, and biliary disease, or for post-transplant evaluation. | **Class B** |
| 76 | Image- intensified fluoroscopic x-ray system | An image-intensified fluoroscopic x-ray system is a device intended to visualize anatomical structures by converting a pattern of x-radiation into a visible image through electronic amplification. | **Class C** |

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| 77 | Indirect flat panel x-ray detector | An electrically-powered, cassette-like device intended to be used as part of an x-ray system to detect x-ray images following exposure, and create a digital signal; it is not dedicated to imaging of a specific anatomy. It may be used in place of a fixed detector in x-ray imaging systems, e.g., as part of a digital imaging conversion system. | **Class B** |
| 78 | Integrated ultrasound/electrocardiograph/stethoscope unit | An electrically-powered modular device intended for general medical examination using ultrasound, electrocardiograph (ECG) and auscultation modalities, with a user interface that enables synchronized data display and recording. | **Class B** |
| 79 | Intracardiac ultrasound imaging catheter, single-use | A flexible tube with an ultrasonic imaging transducer at its distal tip intended for intracardiac echocardiography to enable intracardiac and possibly great vessel (e.g., pulmonary artery) visualization for the assessment of cardiac anatomy and physiology, and visualization of other devices in the heart; it is not intended for peripheral vascular or coronary artery insertion/imaging. It may be steerable. This is a single-use device. | **Class D** |
| 80 | Intracorporeal ultrasound transducer contouring attachment | Intended to be used with a hand-held ultrasound imaging system transducer to provide means to replace the position of a needle guide. | **Class B** |
| 81 | Intracorporeal central nervous system ultrasound transducer/probe | An ultrasonic probe intended to be used temporarily in central nervous system surgery. It is designed to be placed at the surgical site to take local images during surgery. | **Class D** |
| 82 | Intraoperative ultrasound imaging transducer cover | A sterile sheath intended to be used as a physical barrier for protection against the effects of environmental exposure (e.g., body fluids, gels) and/or to maintain the required hygienic level of an ultrasound imaging system transducer (probe) used intraoperatively, e.g., on internal organs, during an ultrasound examination. This is a single-use device. | **Class B** |
| 83 | Intraoral dental x-ray system, mobile/portable/ stationary | A diagnostic dental x-ray system intended to generate, control and record the absorption pattern of x-ray beams for general-purpose, routine, dental radiography examinations involving the diagnosis and treatment (e.g., surgical or interventional) of diseases of the teeth, jaw and oral cavity structures. | **Class C** |
| 84 | Intravascular optical coherence tomography catheter | A catheter and a guide wire intended for use to observe a cross section of blood vessels using an optical fiber by light. | **Class C** |
| 85 | Intravascular ultrasound imaging catheter | A flexible tube with an ultrasound imaging transducer enclosed in a fluid-resistant or waterproof acoustically- and electrically-insulated housing, intended for insertion into the vascular system (i.e., peripheral vascular system) by an operator; it is not intended for intracardial insertion/imaging. Also known as a vascular ultrasound transducer. | **Class C** |
| 86 | Invasive vascular ultrasound system | A mains electricity (AC-powered) device assembly intended to invasively locate and assess the extent of vascular flow restriction (e.g., clots, stenosis, mechanical damage) using ultrasound/ Doppler/transit time technology during procedures involving vascular surgery. It may also provide additional measurements (e.g., blood pressure, vascular resistance). | **Class C** |

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| 87 | Invasive vascular ultrasound system probe | A hand-operated component of an invasive vascular ultrasound system intended to be used perioperatively/intraoperatively to measure the flow of blood in an isolated blood vessel, by being applied to the outside of the vessel, using ultrasonic/Doppler/transit time technology. It may also be used for cross-sectional visualization/imaging. This is a reusable device. | **Class C** |
| 88 | Limited view field X-ray computed tomography system | A diagnostic X-ray computed tomography (CT) system equipped with a gantry intended exclusively for taking images of the area from the head to the neck or the extremities. | **Class C** |
| 89 | Mammographic MRI system, Permanent magnet | A magnetic resonance (MR) diagnostic imaging device specifically intended for breast imaging. The device uses a permanent magnet, and can be stationary, mobile, or portable. | **Class C** |
| 90 | Mammographic MRI system, Resistive magnet | A magnetic resonance (MR) diagnostic imaging device specifically intended for breast imaging. The device uses a resistive magnet, and can be stationary, mobile, or portable. | **Class C** |
| 91 | Mammographic MRI system, Superconducting magnet | A magnetic resonance (MR) diagnostic imaging device specifically intended for breast imaging. The device uses a superconducting magnet, and can be stationary, mobile, or portable. | **Class C** |
| 92 | Mammographic stereotactic biopsy system | An assembly of devices intended to be used in conjunction with mammography to insert biopsy devices, typically designated needles, into a breast in order to extract a biopsy of a suspect tumour for diagnostic purposes. | **Class B** |
| 93 | Mammographic x-ray system (portable/mobile/stationary) | A mammographic x-ray system is a device intended to be used to produce radiographs of the breast for diagnostic purposes. It may be used intraoperatively. | **Class C** |
| 94 | Mammographic x-ray system stereotactic unit | A device intended to be used with a diagnostic mammographic x-ray system (not included) to take multiple pictures of a breast from different angles in order to determine the exact position of a lesion in the breast. This device or technique may be built-in to some diagnostic x-ray systems for mammography. | **Class B** |
| 95 | Mammographic x-ray system, mobile/stationary/portable | An assembly of devices specifically intended to image the breast for diagnostic purposes. It may be used for breast cancer screening and in conjunction with the placement of biopsy markers and stereotactic biopsy and lesion localization equipment requiring x-ray guidance. | **Class C** |
| 96 | Manual contrast medium injection system | An assembly of devices intended for the manual-only injection of contrast media into the blood or lymphatic vessels of a patient for a diagnostic imaging procedure; it enables the operator to manually control the volume and rate of contrast media administered under pressure. | **Class B** |

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| 97 | Medical image analyzer | Medical image analyzers, including computer-assisted/aided detection (CADe) devices are intended to identify, mark, highlight, or in any other manner direct the clinicians' attention to portions of a radiology image that may reveal abnormalities during interpretation of patient radiology images by the clinicians. This device is not intended to replace the review by a qualified radiologist, and is not intended to be used for triage, or to recommend diagnosis. | **Class B** |
| 98 | Medical x-ray film, screen | A screen x-ray film specifically designed for medical diagnostic imaging applications. It is sensitive primarily to wavelengths of light emitted from an image intensifying screen or other visible light source. This film is not limited to use with x-ray imaging systems but can also be used in a variety of diagnostic imaging modalities using image intensifier technology or matrix formatters to output images, e.g., nuclear medicine or ultrasound. | **Class B** |
| 99 | MR/CT roadmap (interpretive software) | A stand alone software intended to synchronize live fluoroscopy images with previously acquired MRA/CTA datasets. This may be used as an aid in applications such as image-guided surgeries, calibrating the contrast medium doses, and needle guidance, etc. | **Class C** |
| 100 | MRI contrast medium injection system, mobile/stationary | An assembly of devices intended to inject contrast media through a small catheter and into the vascular system for magnetic resonance imaging (MRI) procedures (e.g., spine, head, gastrointestinal, or vascular diagnostic procedures using MRI). It may interface with the MRI system or a monitoring device to control timing of contrast injections. | **Class C** |
| 101 | MRI image interpretive software | An interpretive software program intended to be used to analyse magnetic resonance imaging (MRI) data to detect and localize suspected abnormalities and sometimes provide results as clinically relevant tags; it may additionally be intended for three-dimensional (3-D) model creation slice-based images (segmentation). It may utilize artificial intelligence (AI) and deep learning techniques. | **Class C** |
| 102 | MRI planner (radiotherapy planning application software) | It is a stand alone software product intended to enable a completely MRI-only workflow in radiotherapy planning. It achieves this by analyzing a dedicated MR image and generating a synthetic CT image that can replace the conventional CT in the treatment planning process. In addition, the software may also perform automated contouring of risk organs in certain anatomies. | **Class C** |
| 103 | MRI radio frequency coil | This radio frequency coil, as a component of a medical MRI system, is intended to act as a transmitter, receiver, or both a transmitter and receiver of RF pulses necessary for diagnostic magnetic resonance imaging (MRI) procedures. It is intended to be used to enhance image resolution by improving signal to noise characteristics. | **Class B** |

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| 104 | MRI system application software | It is a standalone software application that is intended to be used for viewing, post-processing and quantitative evaluation of magnetic resonance (MR) images for applications such as quantitative cardiovascular computed tomography (CT) evaluation, determination of the triglyceride fat fraction in MR images of the liver, multi slice and gradient echo image analysis, etc. It does not drive MRI systems. | **Class C** |
| 105 | MRI system synchronizer | A physiological monitoring unit intended to be used as a component of a diagnostic magnetic resonance imaging (MRI) system, for synchronize image formation or data collection with a specific measurable physiological parameter, e.g., the beginning of a patient's respiratory or cardiac cycle. It is primarily used for the purpose of artifact reduction or enhancement of signal-to-noise ratios in various real-time or dynamic MRI applications. | **Class B** |
| 106 | MRI system table, powered | A powered/programmable table with electronic and/or software controls intended to position and support a patient during magnetic resonance imaging (MRI) examinations. | **Class B** |
| 107 | MRI system workstation | A standalone image-processing workstation that is intended to be networked with one or more magnetic resonance imaging (MRI) systems. The workstation may have any type of hardware, or any type of configuration. It is not intended to control or directly manipulate the diagnostic imaging device. It is intended to process MRI images and provide valuable information that allow decision making, evaluation or diagnosis of the patient's pathologic conditions. | **Class B** |
| 108 | MRI-patient physiologic monitoring system | A mobile assembly of devices intended for continuous assessment of several vital physiologic parameters (e.g., ECG, blood pressure, heart rate, temperature, cardiac output, apnoea, and respiratory/anaesthetic gas concentrations, etc.) of infant to adult intensive care patients during a magnetic resonance imaging (MRI) procedure. | **Class C** |
| 109 | Multi-modality diagnostic x-ray system (full body CT/fluoroscopic x-ray system) | An assembly of diagnostic x-ray devices intended to acquire, display and process images from any part of the body (full-body) incorporating the techniques of more than one x-ray imaging modality, typically including real-time fluoroscopy, two-dimensional (2D) radiography, and computed tomography (CT); it is not a single-modality system. | **Class C** |
| 110 | Neurosurgical ultrasound navigation system application software | An individual software program or group of programs, routines or algorithms that add specific image processing and/or analysis capabilities to a neurosurgical ultrasound (US) navigation system. It does not drive the ultrasound navigation system. | **Class C** |
| 111 | Neurosurgical ultrasound navigation system optical tracking unit | A component of a neurosurgical ultrasound (US) navigation system intended to track the position of all the localizers/spatial markers during intraoperative imaging and to supply the ultrasound system (not included) with valid positional data. | **Class B** |

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| 112 | Nonfetal ultrasonic monitor | A nonfetal ultrasonic monitor is a device that projects a continuous high frequency sound wave into body tissue other than a fetus to determine frequency changes (doppler shift) in the reflected wave and is intended for use in the investigation of nonfetal blood flow and other nonfetal body tissues in motion. | **Class B** |
| 113 | Non-image- intensified fluoroscopic x-ray system | A non-image-intensified fluoroscopic x-ray system is a device intended to be used to visualize anatomical structures by using a fluorescent screen to convert a pattern of X-ray radiation into a visible image. | **Class C** |
| 114 | Noninvasive vascular ultrasound probe | A hand-operated component of a vascular ultrasound system intended to measure the flow of blood noninvasively by measuring flow in underlying vasculature from the body surface pre-/post-operatively, using ultrasonic/Doppler/transit time technology. It may also be used for cross-sectional visualization/imaging. | **Class B** |
| 115 | Noninvasive vascular ultrasound system | An electrically-powered device assembly intended to noninvasively locate and assess the extent of vascular (venous and arterial) flow restriction (e.g., clots, stenosis, mechanical damage) by measuring blood flow rate using ultrasound/Doppler/transit time technology. It may also be used to detect the foetal heartbeat. | **Class C** |
| 116 | Nuclear electrocardiogram synchronizer/Nuclear medicine system synchronizer | A nuclear electrocardiograph synchronizer is a device intended for use in nuclear radiology to relate the time of image formation to the cardiac cycle during the production of dynamic cardiac images. | **Class B** |
| 117 | Nuclear medicine data processing system | A data processing system specifically dedicated for nuclear medicine. The system is used for various types of filter processing, image display, clinical analysis, management of image storage, etc. The system may have a control system for directly operating a diagnostic imaging unit. This system can deliver or receive data online or offline, and has a configuration that can provide functions such as processing, manipulating, and displaying a patient's images and information collected with the nuclear medicine scan. | **Class C** |
| 118 | Nuclear medicine system workstation | A standalone imaging workstation specifically intended to create network connection with one or more nuclear imaging devices, such as gamma camera, PET device, and SPECT device. The workstation may have any type of hardware, or any type of configuration. It does not have controls for the direct manipulation of the imaging device. | **Class B** |
| 119 | Nuclear sealed source for absorption compensation | A sealed radioisotope intended to be used for the correction of absorption of radiation from a diagnostic radioisotope by organs and tissues to improve quantitative capability of diagnostic imaging of the nuclear imaging system (PET or SPECT devices), thereby improving accuracy of diagnosis. | **Class B** |

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| 120 | Nuclear tomography system/nuclear medicine system | A nuclear tomography/medicine system is a device intended to detect nuclear radiation in the body and produce images of a specific cross-sectional plane of the body by blurring or eliminating detail from other planes. | **Class C** |
| 121 | Nuclear whole body scanner | A nuclear whole body scanner is a device intended to measure and image the distribution of radionuclides in the body by means of a wide- aperture detector whose position moves in one direction with respect to the patient. | **Class C** |
| 122 | Oesophageal ultrasound imaging transducer (oesophagal endosonography probe/transducer) | An ultrasound imaging transducer assembly intended to be inserted and positioned in the oesophagus to obtain ultrasound images of the heart and/or to navigate devices requiring ultrasound guidance and placement (e.g., endoscopy equipment or needle biopsy equipment). | **Class B** |
| 123 | Ophthalmic ultrasound imaging transducer | An ultrasound imaging transducer that is a hand-held device intended to be moved over the intact surface of a patient's eye during imaging applications involving the examination of the lens. This is a reusable device. | **Class B** |
| 124 | Optical coherence tomography (OCT) imaging system | The OCT (optical coherence tomography) diagnostic imaging system is intended for use in imaging of tissue characteristics and shapes of various sites (e.g., blood vessel, abdomen, lung) using near-infrared rays, without the need to obtain tissues surgically. This system may or may not contain a software package that supports the taking of both still and real-time images, and is used to diagnose anatomic abnormalities in tissues and to examine functional and anatomic features. | **Class C** |
| 125 | Optoacoustic/ultrasound imaging system | An assembly of electrically-powered devices intended for imaging and analysis of soft-tissue and soft-tissue vasculature using combined optoacoustic (photoacoustic: pulsed near-infrared) and ultrasound (US) imaging. | **Class B** |
| 126 | Orthopaedic x-ray ruler | A device used in an orthopaedic clinical setting intended to be used to establish an accurate measurement of length or size related to a bone structure (i.e., length, thickness, or other aspects) when this is being viewed by the surgeon during fluoroscopy. It includes a series of notches and holes that clearly show up on the x-ray image demonstrating the distances of the viewed bone. | **Class A** |
| 127 | Panoramic digital X-ray sensor | A sensor used in combination with a diagnostic digital dental X-ray imaging device that is specifically intended for panoramic imaging of teeth, jaw, and oral structures. | **Class B** |
| 128 | Panoramic/tomographic dental x-ray system (orthopantomography system) application software | An application or operating data program intended for use in, or together with a panoramic/tomographic dental x-ray system configuration for image analysis. | **Class C** |

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| 129 | Paranasal ultrasound probe | An ultrasound transducer assembly intended to be inserted into and positioned in the paranasal sinuses for diagnostic imaging purposes. The device is also called an endoscopic ultrasound probe or ultrasound endoscopic transducer to be used in the paranasal sinuses. The device is typically incorporated in or used in combination with a device that requires ultrasonography guidance or ultrasonic wave generation, such as an endoscopic device or a needle biopsy device. | **Class B** |
| 130 | PET infusion system | An assembly of devices intended to deliver accurate doses of Fluorine-18 (18F) Fluorodeoxyglucose (FDG) radiopharmaceuticals (not included) and commonly used flushing solutions to patients during molecular imaging (nuclear medicine) diagnostic procedures. It may also be used to provide effective radiation shielding to medical personnel from 18F radiation exposure during nuclear medicine diagnostic procedures. | **Class C** |
| 131 | PET system | An assembly of devices comprising a diagnostic positron emission tomography (PET) imaging system intended to detect, record, quantify and analyse photon emission patterns to produce three-dimensional (3-D) tomographic digital cross-sectional physiological images of the patient. | **Class C** |
| 132 | PET system application software | An individual software program or group of programs, routines or algorithms that are intended to add specific image processing and/or analysis capabilities to a positron emission tomography (PET) imaging system configuration. Not intended to drive, control or operate the PET system. | **Class B** |
| 133 | PET/CT system | A diagnostic radiological imaging system that is a combination of a positron emission tomography (PET) camera system for nuclear medicine (NM) images, and a computed tomography (CT) camera system for x-ray images. The PET and CT portions of the system may be used independently or in combination. | **Class C** |
| 134 | PET/MRI system | A diagnostic radiological imaging system that is a combination of a positron emission tomography (PET) camera system for nuclear medicine (NM) images, and a magnetic resonance imaging (MRI) system for magnetic resonance images. The PET and MRI portions of the system may be used independently or in combination. | **Class C** |
| 135 | Photofluorographic x-ray system | A photofluorographic x-ray system is a device that includes a fluoroscopic x-ray unit and a camera intended to be used to produce, then photograph, a fluoroscopic image of the body. | **Class C** |
| 136 | Pneumoencephalographic chair | It is intended to support and position a patient during pneumoencephalography (x-ray imaging of the brain). | **Class B** |
| 137 | Positron CT-combined SPECT system (PET/SPECT system) | A system intended to perform both SPECT examination and positron CT (PET) examination. | **Class C** |
| 138 | Radiographic film cassette/X-ray cassette | A radiographic film cassette is a device intended for use during diagnostic x-ray procedures to hold a radiographic film in close contact with an x-ray intensifying screen and to provide a light-proof enclosure to prevent direct exposure of radiographic film. | **Class B** |

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| 139 | Radiographic film/cassette changer | A radiographic film/cassette changer is a device intended to be used during a radiologic procedure to move a radiographic film or cassette between x-ray exposures and to position it during the exposure. | **Class B** |
| 140 | Radiographic film/cassette changer programmer | A radiographic film/cassette changer programmer is a device intended to be used to control the operations of a film or cassette changer during serial medical radiography. | **Class B** |
| 141 | Radiologic quality assurance instrument | A radiologic quality assurance instrument is a device intended for medical purposes to measure a physical characteristic associated with another radiologic device. | **Class A** |
| 142 | Radiological computer aided triage and notification software | Radiological computer aided triage and notification software is an image processing software intended to aid in prioritization and triage of radiological medical images. The device uses computer aided image analysis of radiologic images for identification of suspicious lesions. | **Class C** |
| 143 | Radiological computer-assisted diagnostic software for lesions suspicious of cancer | A radiological computer-assisted diagnostic software is an image processing device intended to aid in the characterization of lesions as suspicious for cancer identified on acquired medical images such as magnetic resonance, mammography, radiography, or computed tomography. The device characterizes lesions based on features or information extracted from the images and provides information about the lesion(s) to the user. | **Class C** |
| 144 | Radionuclide dose calibrator | A radionuclide dose calibrator is a radiation detection device intended to assay radionuclides before their administration to patients. | **Class B** |
| 145 | Radionuclide rebreathing system | A radionuclide rebreathing system is a device intended to be used to contain a gaseous or volatile radionuclide or a radionuclide-labeled aerosol and permit it to be respired by the patient during nuclear medicine ventilatory tests (testing process of exchange between the lungs and the atmosphere). | **Class C** |
| 146 | Rectal/vaginal ultrasound imaging transducer | An invasive component of an ultrasound imaging assembly intended to be positioned within the vagina and/or rectum, either manually or under endoscopic guidance, for ultrasound imaging from within the vagina/rectum. It may be intended for wired or wireless data transfer and may be intended for use with a dedicated ultrasound system or with an off-the-shelf device (e.g., smartphone) with dedicated software installed. This is a reusable device. | **Class B** |
| 147 | Software for electrocardiograph with ultrasonic diagnostic system | A software which is intended to process data obtained from an electrocardiograph with ultrasound diagnostic system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored. | **Class B** |
| 148 | SPECT system application software | An individual software program or group of programs, routines or algorithms that add specific image processing and/or analysis capabilities to a positron emission tomography (PET) imaging system configuration. It is not an operating software or firmware. | **Class B** |

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| 149 | SPECT system, annular detector array | An assembly of devices comprising a diagnostic, stationary, single photon emission computed tomography (SPECT) system intended exclusively for use in tomographic imaging applications. It detects, records, quantifies and analyses radionuclide emissions produced during the decay of radiopharmaceuticals or other radiation emitting materials injected into, or ingested by, a patient. | **Class C** |
| 150 | SPECT system, rotating detector head | An assembly of devices comprising a diagnostic single photon emission computed tomography (SPECT) system that is a three-dimensional (3-D) tomographic imaging gamma camera-based system intended to detect, record, quantify and analyse radionuclide emissions (primarily gamma rays) produced during the decay of radiopharmaceuticals or other radiation emitting materials injected into, or ingested by, a patient. | **Class C** |
| 151 | SPECT/CT system | An assembly of diagnostic devices that is a combination of a single photon emission computed tomography (SPECT) camera system for nuclear medicine (NM) images, and a computed tomography (CT) camera system for x-ray images. The SPECT and CT portions of the system may be used independently or in combination and the images may be transferred to other systems for radiation therapy planning or additional processing. | **Class C** |
| 152 | Spot-film device | A spot-film device is an electromechanical component of a fluoroscopic x-ray system that is intended to be used for medical purposes to position a radiographic film cassette to obtain radiographs during fluoroscopy. | **Class B** |
| 153 | Surgical ultrasound imaging transducer | A hand-held ultrasound imaging transducer assembly intended to be positioned within a surgical site for localized intraoperative imaging applications. This is a reusable device. | **Class C** |
| 154 | Thyroid-uptake nuclear medicine system | An assembly of diagnostic devices that comprise a non-imaging nuclear medicine system intended primarily for radioactive iodine related thyroid uptake measurement and analysis applications. | **Class B** |
| 155 | Tissue specimen x-ray tomography system | An assembly of devices intended to produce an x-ray image of a tissue sample (e.g., stereotactic biopsy cores taken during mammographic procedures) and/or an amputated body part, by generating and controlling x-ray beams and recording the absorption patterns of the x-rays. It is not intended for direct patient use. | **Class A** |
| 156 | Transilluminator for breast evaluation/Breast transilluminator (Diaphanoscope) | An electrically powered device intended to transmit low intensity emissions of visible light and near-infrared radiation (approximately 700-1050 nanometers (nm)), through the breast to visualize translucent tissue for the diagnosis of cancer, other conditions, diseases, or abnormalities. | **Class B** |
| 157 | Transoesophageal vascular ultrasound monitor | A mains electricity (AC-powered) device intended to be used for monitoring cardiac output and/or fluid status through connection to a dedicated probe, which is placed in the oesophagus to measure blood flow in the descending aorta. It may be used during a surgical procedure or in intensive care. | **Class B** |

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| 158 | Transoesophageal vascular ultrasound probe | A device intended to be inserted into the oesophagus, orally or nasally, to continuously measure blood flow in the descending aorta by ultrasonic Doppler technology for assessment of cardiac output and/or fluid status. It is typically used during general anaesthesia or in intensive care. This is a single-use device. | **Class B** |
| 159 | Ultrasonic amplifier | A unit intended for use to amplify signals transmitted from the probe of an ultrasound imaging system. This is used with an ultrasound system in the event the quality of original data transfer is lowered by the distance between the console and the imaging probe in the ultrasound system. | **Class B** |
| 160 | Ultrasonic pulsed doppler imaging system | An ultrasonic pulsed doppler imaging system is a device that combines the features of continuous wave doppler-effect technology with pulsed-echo effect technology and is intended to determine stationary body tissue characteristics, such as depth or location of tissue interfaces or dynamic tissue characteristics such as velocity of blood or tissue motion. | **Class B** |
| 161 | Ultrasonic pulsed echo imaging system | An ultrasonic pulsed echo imaging system is a device intended to project a pulsed sound beam into body tissue to determine the depth or location of the tissue interfaces and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver. | **Class B** |
| 162 | Ultrasound aspiration biopsy procedure kit | A collection of sterile devices, that includes a biopsy needle and other supplies, intended to perform an ultrasound-guided aspiration sampling of tissue. This is a single-use device. | **Class B** |
| 163 | Ultrasound contrast medium, transuterine administration | A substance/formulation (e.g., solution, gel, foam) intended to be administered into the female reproductive tract, via the vagina/uterus, to enhance diagnostic ultrasound images, typically for the evaluation of the uterine cavity and/or fallopian tube patency. (Invasive devices for application not included) | **Class B** |
| 164 | Ultrasound endoscope balloon, natural rubber latex | A sterile balloon-like cap made of Hevea natural rubber latex (NRL) intended to be placed on the distal end of an ultrasound endoscope and inflated to make contact with the wall of the viscus to enable a higher-quality ultrasound image during echo-endoscopy, typically of the gastrointestinal or respiratory tract. | **Class B** |
| 165 | Ultrasound endoscope balloon, synthetic polymer | A sterile balloon-like cap made of a synthetic-polymer (e.g., silicone) intended to be placed on the distal end of an ultrasound endoscope and inflated to make contact with the wall of the viscus to enable a higher-quality ultrasound image during echo-endoscopy, typically of the gastrointestinal or respiratory tract. | **Class B** |
| 166 | Ultrasound imaging system application software | An individual software program or group of programs, routines or algorithms that add specific image processing and/or analysis capabilities to a diagnostic ultrasound system configuration. | **Class B** |

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| 167 | Ultrasound imaging system multi-transducer connection unit | An electronic device intended to be used with an ultrasound (US) imaging system to enable the simultaneous connection of multiple hand-held US transducers (not included) so the user can conveniently switch between transducers as required. | **Class B** |
| 168 | Ultrasound imaging system operation software | Mainframe or personal computer (PC) based operating system software (or firmware) specific to the central processing unit (CPU) incorporated into a diagnostic ultrasound system configuration. | **Class B** |
| 169 | Ultrasound imaging system operator console | A device that is a component of a diagnostic ultrasound imaging system intended to function as the primary control panel. It includes hardware and software that allows for image display, processing, analysis, archiving and retrieval. It contains the primary controls for the direct operation of the ultrasound system. | **Class B** |
| 170 | Ultrasound imaging system tracking positioner, reusable (ultrasound transducer bracket) | A metal or plastic bracket intended to be applied to a hand-held ultrasound (US) transducer for the repeatable positioning (detach from/reattach to same place) of an electromagnetic (EM) sensor and/or needle guide on the transducer. It may be used in conjunction with an EM device tracking system and is intended for applications involving needle guidance and tracking such as ablation, core tissue biopsy, fluid aspiration, therapeutic delivery and vascular access. (transducer and sensor are not included) | **Class B** |
| 171 | Ultrasound imaging transducer positioning unit | A unit, which is an accessory to diagnostic ultrasound system, intended to position an ultrasound system imaging transducer that is inserted into the body through an endoscope and allow monitoring of the movement after placement. | **Class B** |
| 172 | Ultrasound imaging transducer washer-disinfector (chemical) | A dedicated electrically-powered unit intended to be used to wash and disinfect ultrasound imaging transducers with the use of appropriate cleaning methods and chemical disinfection. Not intended for end-point disinfection/sterilization. | **Class B** |
| 173 | Ultrasound system synchronizer | A physiological monitoring device intended to be used as a component in a diagnostic ultrasound system, to synchronize imaging acquisition and data collection with specific measurable, physiological parameters, such as the starting point of a patient's respiratory or cardiac cycle. It is used mainly to reduce artifacts and to increase the signal-to-noise ratio in real-time ultrasonic imaging and in video imaging. | **Class B** |
| 174 | Needle guide positioning system for ultrasound-guided laser thermal therapy | An assembly of noninvasive devices intended for use during soft-tissue lesion treatment by ultrasound-guided laser thermal therapy, to provide software-based simulation of tissue thermal damage for assisting the manual positioning of percutaneous needles through which laser applicators (not included) are introduced. | **Class B** |

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| 175 | Vascular ultrasound system control unit | A mains electricity (AC-powered) external device intended to be used to indicate (visually and/or sonically) blood flow in a peripheral blood vessel, through connection to a dedicated probe/catheter (not included), using ultrasound/Doppler/transit time technology. It may be intended to locate and assess the extent of vascular flow restriction (e.g., clots, stenosis, mechanical damage) or to monitor blood flow in association with microvascular surgery. | **Class B** |
| 176 | X-ray film ruler | A device used in radiology intended to superimpose accurate measurements of length (i.e., inches or millimetres) onto an x-ray film so that these measurements remain as a permanent feature of that x-ray against the anatomical structure that has been captured. | **Class A** |
| 177 | X-ray image intensifier | A device intended to convert an x-ray image into a light image, then to an electronic image and finally back to a light-based image of diminished size and increased brightness. It is primarily used in fluoroscopic, angiographic, cine-fluorographic x-ray, and digital x-ray applications as it outputs an image small enough to be coupled to cine, television or spot-film cameras. | **Class B** |
| 178 | X-ray system computer, diagnostic, general-purpose | A dedicated mainframe computer, personal computer (PC) or PC based platform and associated hardware, firmware, and operating system software intended to be used specifically to control and monitor the operation of a general-purpose medical x-ray system and associated image processing, display and analysis functions. | **Class C** |
| 179 | X-ray system synchronizer | A physiological monitoring unit intended to be used as a component of a diagnostic x-ray system, e.g., fluoroscopy, angiography or general-purpose, to synchronize image formation or data collection with a specific measurable physiological parameter, e.g., the beginning of a patient's respiratory or cardiac cycle. It is primarily used for the purpose of artifact reduction or enhancement of signal-to-noise ratios in various real-time or dynamic diagnostic x-ray applications. It is sometimes referred to as a gated imaging accessory or trigger. | **Class C** |
| 180 | X-ray/CT combined cardiovascular diagnostic X-ray system | A system combining a diagnostic X-ray computed tomography (CT) and a diagnostic cardiovascular fluoroscopy system. | **Class C** |
| 181 | Ultrasound needle guide, reusable | A non-powered device intended to direct a sharp needle (not included) into its proper course when performing ultrasound-guided clinical and/or surgical procedure including biopsies. This is a reusable device intended to be sterilized prior to use. | **Class B** |
| 182 | Ultrasound needle guide, single-use | A non-powered, disposable device intended to direct a sharp needle (not included) into its proper course when performing ultrasound-guided clinical and/or surgical procedure including biopsies. This is a single-use device. | **Class B** |
| 183 | Positron camera | A positron camera is a device intended to image the distribution of positron-emitting radionuclides in the body. | **Class B** |

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| 184 | Scintillation (gamma) camera | A scintillation (gamma) camera is a device intended to image the distribution of radionuclides in the body by means of a photon radiation detector. | **Class B** |
| 185 | Nuclear whole body counter | A nuclear whole body counter is a device intended to measure the amount of radioactive material in the entire body. | **Class B** |
| 186 | Nuclear rectilinear scanner | A nuclear rectilinear scanner is a device intended to image the distribution of radionuclides in the body by means of a detector (or detectors) whose position moves in two directions with respect to the patient. | **Class B** |
| 187 | Nuclear uptake probe | A nuclear uptake probe is a device intended to measure the amount of radionuclide taken up by a particular organ or body region | **Class B** |