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Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation

FDA Bhawan, Kotla Road,
New Delhi – 110002
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Notice

Subject: Risk classification list of medical devices pertaining to Oncology - Reg.

Consequent to the publication of draft list 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 Oncology, under the Medical Devices Rules, 2017.

The list of medical devices pertaining to Oncology 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 the guidance to the applicant who intend to furnish applications for manufacturing/import of medical devices under the Medical Devices Rules, 2017. However, a device may have 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.

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Drugs Controller General (I)

Appendix A

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Notice

Classification of Medical Devices Pertaining to Oncology

S. No.	Device name	Intended use	Risk Classification
1	Accelerator system chair	A component of a therapeutic accelerator system intended to support and position a seated patient during radiation therapy treatments involving the use of either a medical linear accelerator or non-linear accelerator.	**Class C**
2	Accelerator system quality assurance device	An instrument specifically intended to be used to check the calibration and performance of linear and non-linear medical accelerator systems used for radiation therapy applications, for quality assurance (QA) purposes.	**Class C**
3	Alternating electric field antimitotic cancer treatment system	An assembly of portable devices intended to apply low-intensity, intermediate-frequency (100-300 kHz) alternating electric fields to treat certain forms of recurrent or newly-diagnosed cancer; typically glioblastoma multiforme (GBM) [malignant brain tumour].	**Class D**
4	Alternating electric field antimitotic cancer treatment system transducer array	A head-worn component of an alternating electric field cancer treatment system intended to convert intermediate-frequency (100-300 kHz) alternating electric current to low-intensity alternating electric fields to treat certain forms of recurrent or newly-diagnosed cancer; typically glioblastoma multiforme (GBM) [malignant brain tumour].	**Class D**
5	Alternating electric field antimitotic cancer treatment system generator	A portable, battery-powered component of an alternating electric field cancer treatment system intended to generate intermediate-frequency (100-300 kHz) alternating electric current to treat certain forms of recurrent or newly-diagnosed cancer; typically glioblastoma multiforme (GBM) [malignant brain tumour].	**Class C**
6	Anorectal brachytherapy system applicator, remote-afterloading	A remote afterloading brachytherapy applicator specifically intended for use in radiation therapy treatments of the rectum and/or anus.	**Class C**
7	Anorectal brachytherapy system applicator, manual	A manual brachytherapy applicator specifically intended to be used in radiation therapy treatments of the rectum and/or anus.	**Class C**
8	Balloon kyphoplasty kit	A collection of sterile surgical instruments and devices intended to be used for the reduction of vertebral compression fractures (VCFs) caused by trauma, cancer, or osteoporosis during a minimally invasive procedure commonly known as balloon kyphoplasty. It typically consists of a bone access needle, an osteo introducer, an inflation syringe, and the inflatable bone tamp (implantable devices such as fillers/cements not included). This is a single-use device.	**Class B**

9	Bladder instillation buffer solution	A sterile buffer solution intended to be used exclusively for bladder instillation to help create an optimal environment necessary for the effective treatment of superficial bladder cancer with a chemotherapy agent. This does not include pharmaceuticals.	**Class B**
10	Brachytherapy source spacer	A sterile, bioabsorbable device intended to separate radioactive sources of the seed type that are permanently implanted in close proximity to a selected localized tumour, to increase the distribution of radioactivity to the tumour.	**Class D**
11	Brachytherapy system remote-afterloading operator console	A mains electricity (AC-powered) component of a remote- afterloading brachytherapy system intended to function as the primary control panel for the remote afterloader. It may also be intended to interface with other devices (e.g., radiation therapy treatment planning computer) as part of a picture archiving and communication system (PACS).	**Class C**
12	Breast 3-D infrared imaging/vascular analysis system	An assembly of mains electricity (AC-powered) devices intended for three-dimensional (3-D) breast imaging and breast vascular analysis, typically used with mammography screening to perform a breast cancer risk examination.	**Class C**
13	Breast brachytherapy system applicator, remote-afterloading	A sterile, remote-afterloading brachytherapy applicator specifically intended for use in radiation therapy treatments of the breast.This is a single-use device.	**Class C**
14	Breast transilluminator	A mains electricity (AC-powered) transilluminating device intended to visualize translucent breast tissue for the diagnosis of cancer, or other conditions, diseases or abnormalities using low intensity emissions of visible light and near-infrared radiation. This device may also be known as a diaphanoscope.	**Class B**
15	Breast ultrasound imaging system, intracorporeal	An assembly of mains electricity (AC-powered) devices intended for intracorporeal (endosonography or endoscopic) ultrasound imaging procedures involving the breast.	**Class C**
16	Breast ultrasound imaging system, extracorporeal	An assembly of mains electricity (AC-powered) devices intended for extracorporeal ultrasound imaging procedures involving the breast.	**Class B**
17	Intraoperative cancer diagnostic probe	An active device intended for detection of breast cancer lesions of various subtypes intraoperatively by checking for tumour side margins.	**Class C**
18	Capsular tension ring	A circular band intended to be used to enhance the mechanical stability of a subluxated crystalline lens capsule in the presence of weak or absent supporting zonules.	**Class C**
19	Cervical cone knife, single-use	A surgical, manually-operated, instrument that is inserted into the vagina and intended for excising a sample of abnormal tissue, e.g., indicated by the presence of precancerous changes, from the cervix. This is a sterile, single-use device.	**Class A**

20	Cervical cytology scraper, single-use	A hand-held, manual surgical instrument intended to scrape and retrieve cytological material from the surface of the cervix (neck of the uterus) or vaginal area for pathological examination and diagnosis, often for the detection of cervical cancer. This is a sterile, single-use device.	**Class A**
21	Colonic cytology sampling set	A collection of devices intended to collect exfoliated colonic cells (colonocytes) from the surface of human rectal mucosa for colorectal cancer investigation and/or patient screening. It typically includes a proctoscope with obturator and a hand-operated, syringe-type, air pump with a sampling balloon. This is a single-use device.	**Class B**
22	Computer vision/Machine learning-aided software application for cancer detection	A standalone software application intended to be used to scan radiological images (X-ray, CT scan, etc.) in order to screen/diagnose for cancerous tissues using machine learning-based training models and computer vision.	**Class C**
23	Coronary artery brachytherapy system applicator, manual-afterloading	A sterile flexible tube intended to deliver/remove radiation therapy sources into/from a coronary artery, typically into the lumen of an implanted stent, as part of a manual-afterloading brachytherapy system. This is a single-use device.	**Class D**
24	Cryosurgical set/ Cryoablation system	A collection of sterile, disposable devices intended for use in conjunction with a cryosurgical unit as well as monitoring and other devices to perform a surgical technique that involves freezing a targeted area of tissue to damage and destroy cancer cells in the unwanted portions.	**Class C**
25	Electrocancer therapy system	An assembly of devices intended for the treatment of tumours and the destruction of cancerous cells using low-voltage direct current of small intensity delivered via electrodes placed across the affected body area.	**Class C**
26	Electronic clinical breast examination system	A portable assembly of devices intended to electronically measure, map, document and store information about breast lesions/masses with regard to shape, size, location, consistency/relative hardness during a clinical breast examination (CBE).	**Class B**
27	Electroporation therapy system	A mobile assembly of devices intended to apply electrical impulses to the tissue to enable electroporation for the delivery of chemotherapeutic or genetic (DNA/RNA) materials. This does not include pharmaceuticals or biological materials.	**Class C**
28	Electroporation therapy system endoscopic applicator	A sterile, patient-contact component of an electroporation therapy system intended to fit onto the distal tip of an endoscope and connect to an electroporation therapy system generator to deliver electrical impulses to tissues during endoscopy as part of electroporation therapy.	**Class C**

29	Embolization particle, bioabsorbable	A bioabsorbable, implantable bead/microsphere intended to be used to temporarily occlude an artery supplying hyperplastic/neoplastic tissue in a variety of anatomies (e.g., liver, lung, breast, bladder, uterus, head or neck); it does not include a pharmaceutical agent. It is typically available as an injectable solution containing numerous microspheres [e.g., degradable starch microspheres (DSM)].	**Class D**
30	Embolization particle, non-bioabsorbable	A non-bioabsorbable, implantable bead/microsphere intended to be introduced into the peripheral vasculature during an interventional radiology procedure to treat hypervascularized tumours and arteriovenous malformation in a variety of anatomies (e.g., head, neck, spine, liver, genitourinary tract, uterus, gastrointestinal, limbs and lungs). It is typically available as injectable solution containing numerous microspheres [e.g., compressible polyvinyl alcohol (PVA) microspheres] intended to permanently obstruct blood flow to the tumour/malformation.	**Class D**
31	Endocervical aspirator	A collection of devices intended to remove superficial tissue from the mucous membrane lining the cervical canal (endometrium) through manually-powered suction. It typically includes a slender endocervical curette, a syringe, a bulb, and a pipette.	**Class B**
32	Externally-propelled flexible video colonoscope	A non-sterile endoscope intended for the visual examination of the entire adult colon [lower gastrointestinal (GI) tract] to aid in screening and detection of colorectal cancer and other diseases of the lower GI tract. This is a single-use device.	**Class B**
33	Extravascular-circulation hyperthermia system	An assembly of devices intended to produce and control heated fluids circulated within a vessel applied to the body (e.g., vest, mattress, jacket, band, pad, body wrap, catheter, probe) for systemic or localized heating to treat malignant tumours, benign growths, or other disease-related conditions.	**Class B**
34	Extravascular-circulation hyperthermia system applicator, extracorporeal	A vessel applied to the outside of the body (e.g., in the form of a jacket, vest, body wrap, cushion, blanket, or mattress) that incorporates tubing through which heated fluids are circulated for systemic or localized heating to treat malignant tumours, benign growths, or other disease-related conditions. The applicator typically includes a thermometry component that monitors the temperature of the applicator during operation. This is a reusable device.	**Class A**
35	Extravascular-circulation hyperthermia system applicator, intracorporeal	A component of a hyperthermia system that typically consists of catheter-enclosed tubing which is intended to be introduced into the body either manually or endoscopically for localized heating to treat malignant tumours, benign growths, or other disease-related conditions. This may include a thermometry component that monitors the temperature of the applicator during operation. This is a single-use device.	**Class B**

36	Facial prosthesis	An externally-applied device intended to be used as an artificial substitute for parts or sections of the face [e.g., nose, eye(s), eye brows, upper lip] to help restore facial appearance. It may be held in position with magnets or screw-like implants embedded into the patient's facial bone. This includes implantable screws.	**Class C**
37	Fixed-aperture therapeutic x-ray system collimator	A non-automated, x-ray beam-limiting device that is a component of a therapeutic x-ray system and whose opening size/length/shutter assembly is fixed. It is intended for use in radiation therapy applications to limit the effects of scattered radiation and to protect the patient by limiting or eliminating exposure to non-target body areas during treatment. This device is specifically designed for use with an x-ray simulation or therapeutic x-ray system.	**Class C**
38	Flexible fibreoptic bronchoscope	An endoscope intended for the visual examination and treatment of the trachea, bronchi, and lungs. It is inserted through the mouth or nose during bronchoscopy. This device may allow operator to take biopsies and samples of secretions. This is a reusable device.	**Class B**
39	Flexible fibreoptic mediastinoscope	A surgically-invasive endoscope with a flexible inserted portion intended for the visual examination and treatment of the mediastinum (the intrapleural space located behind the sternum). This device is commonly used to examine structures such as lymph nodes during a staging evaluation of lung cancer, or to establish the diagnosis of a tumour that is localized to the mediastinum. This is a reusable device.	**Class B**
40	Flexible ultrasound bronchoscope	An endoscope intended to be used in conjunction with an ultrasound probe for the visual examination and treatment of the trachea, bronchi, and lungs. This device may allow biopsies and access to samples of secretions. This is a reusable device.	**Class B**
41	Flexible video bronchoscope	An endoscope intended for endoscopic procedures of the airways and tracheobronchial tree (i.e., bronchoscopy). This is a reusable device.	**Class B**
42	General-purpose infusion pump, mechanical, reusable	A non-electric, mechanically-powered (e.g., a spring mechanism) device intended for the continuous or intermittent infusion of medication, typically for antibiotic therapy, chemotherapy, or pain management by intravenous (IV), subcutaneous, intramuscular, or epidural routes. It may be used for patient-controlled analgesia (PCA), and may include mechanical indicators for flow and fluid level status. This is a reusable device.	**Class C**
43	General-purpose infusion pump, mechanical, single-use	A portable, non-electric, mechanically-powered device intended for use by healthcare professionals for dispensing a single dose of fluid medication (e.g., for antibiotic therapy, chemotherapy, analgesia). This is a single-use device.	**Class C**

44	Hyperthermia system temperature probe	A device (a probe) intended to be used exclusively to monitor tissue or body temperature during hyperthermia treatments. Depending on the kind of hyperthermia system it is used with, e.g., ultrasound, radio-frequency (RF) or microwave, etc. This is a reusable device.	**Class C**
45	Implantable Vascular port/catheter	A fully-implantable device assembly intended to provide access to arteries/veins (excludes coronary and intracerebral circulation) for infusion (e.g., chemotherapeutic agents, blood transfusions) and/or drainage (e.g., blood).	**Class C**
46	Intracavitary-circulation hyperthermia system	An assembly of electrically-powered devices intended to continuously lavage body cavities (e.g., pleural cavity, peritoneal cavity, bladder lumen) with warmed fluids/chemotherapeutic agents to raise the local temperature and/or enhance the effect of drugs, typically in the treatment of malignancy.	**Class C**
47	Intraoperative gamma radiation detection system probe control unit	An electrically-powered component of an intraoperative gamma radiation detection system intended to detect and quantify gamma radiation emitted from previously-administered radiopharmaceuticals (e.g., localized in sentinel lymph nodes), in conjunction with a dedicated invasive probe (not included). It typically consists of a console with display, audiovisual alarms, and controls.	**Class C**
48	Intraoperative gamma radiation detection system probe	An electrically-powered, invasive component of an intraoperative gamma radiation detection system intended to be introduced into the body during a surgical procedure to detect and quantify gamma radiation emitted from previously-administered radiopharmaceuticals (e.g., localized in sentinel lymph nodes), in conjunction with a dedicated control unit (not included).	**Class C**
49	Intraoperative tumour margin fluorescence imaging system	A set of devices intended for fluorescent imaging of an area within the body using the excitation of an injected fluorophore (e.g., pegulicianine). It is typically used for intraoperative detection of residual cancerous tissue in the resection cavity following removal of the primary specimen during surgical procedure (e.g., lumpectomy). This is a reusable device.	**Class C**
50	Intravascular/intracavitary-circulation hyperthermia system	An assembly of devices intended to circulate warmed fluids or autologous blood through the vasculature or cavity of a targeted anatomical area (e.g., peritoneal/pleural cavities, thorax, abdomen, section of a limb) to treat cancer. It heats the blood/fluids to temperatures up to 43 °C to enhance the effect of drugs [e.g., for intraperitoneal hyperthermic chemotherapy (IPHC)] and help destroy cancer cells.	**Class C**

51	Intravascular/intracavitary-circulation hyperthermia system set (Kit for hyperthermic perfusion)	A collection of non-powered, sterile devices intended for use with an intravascular/intracavitary-circulation hyperthermia system for the circulation of blood/fluid between the patient and the system's extracorporeal circuit during cancer therapy. It typically consists of drains/catheters, tubing, connectors, manual clamps, temperature sensors, and hard or soft reservoirs. This is a single-use device.	**Class B**
52	Microwave ablation system	An assembly of devices consisting of a generator and a probe (and other accessories) intended to generate and transmit microwave energy for localized non-vascular soft-tissue ablation, typically to treat tumours, hydatid cysts and/or menorrhagia.It is intended to be used in percutaneous, laparoscopic, natural orifice or open surgery procedures to ablate tissue typically in the liver, lung, pancreas, kidney, and uterus (e.g., endometrial ablation).	**Class C**
53	Microwave ablation system generator	A mains electricity (AC-powered) device intended to generate microwave energy for localized non-vascular soft-tissue ablation, typically to treat tumours, hydatid cysts and/or menorrhagia (excludes cerebral and coronary tissues). It is intended to be used in percutaneous, laparoscopic, natural orifice or open surgery procedures to ablate tissue typically in the liver, lung, pancreas, kidney, and uterus (e.g., endometrial ablation).	**Class C**
54	Microwave ablation system probe/microwave ablation antenna	A hand-held surgical instrument intended to connect to a microwave ablation system generator to deliver microwaves to a targeted operative site for localized soft-tissue ablation, typically to treat tumours, hydatid cysts and/or menorrhagia. The device is intended to be used in percutaneous, endoscopic [e.g., gastroscopic, laparoscopic], natural orifice or open surgery procedures to ablate tissues (e.g., endometrial ablation).	**Class C**
55	Microwave hyperthermia system	A mains electricity (AC-powered) device assembly intended for controlled heating (i.e., temperatures above 43° Celsius) of the body using microwaves, for the treatment of malignant or benign tumours or other disease conditions [e.g., benign prostatic hyperplasia (BPH), prostatitis]. It may be intended for both whole-body and localized heating of tissues/organs.	**Class C**
56	Microwave hyperthermia system applicator, extracorporeal	A component of a microwave hyperthermia system intended to direct and deliver microwave energy used to produce a systemic or local heating effect.	**Class C**
57	Microwave hyperthermia system applicator, intracorporeal	A component of a microwave hyperthermia system intended to be placed inside the body to deliver microwave energy to produce a systemic or local heating effect. It is also referred to as an interstitial applicator or probe	**Class C**

58	Microwave/electrosurgical system generator	An electrically-powered component of a microwave ablation/electrosurgical system intended to generate both: 1) radio-frequency (RF) electrical current; and 2) microwave energy for subsequent cutting, coagulation, and ablation of soft tissues during an endoscopic or open surgical procedure; it is not dedicated to focal ablation of specific tissues. It is not intended for inert gas electrosurgery.	**Class C**
59	Multi-modality hyperthermia system	A mains electricity (AC-powered) device assembly intended for controlled heating (i.e., temperatures above 43° Celsius) of the body using multiple energy sources, for the treatment of malignant or benign tumours, or other disease conditions (excludes cerebral and coronary tissues). It is intended to achieve whole-body and localized heating of tissues using two or more energy sources [e.g., ultrasound, radio-frequency (RF), microwave, circulating heated fluid].	**Class C**
60	Photopheresis system blood set	A collection of devices intended for use as part of a photopheresis system for extracorporeal photoimmunetherapy to treat immune disorders, especially cutaneous T-cell lymphoma (CTCL). This is a sterile, single-use device.	**Class C**
61	Photopheresis system lamp assembly	An assembly of ultraviolet A (UVA)-emitting tubular strip lights that is an exchangeable component of a photopheresis system, and intended to irradiate blood components during extracorporeal photoimmunetherapy to treat immune disorders, especially cutaneous T-cell lymphoma (CTCL).	**Class C**
62	Polymer-metal oesophageal stent	A non-bioabsorbable, expandable, tubular device intended to be implanted into the oesophagus to maintain luminal patency in strictures and prevent tumour in-growth. It may also be intended to seal oesophageal fistulas, reduce acute bleeding from oesophageal varices, and/or to treat other lesions causing oesophageal leakage (e.g., anastomotic). Disposable devices intended for introduction may be included.	**Class C**
63	Radiation therapy digital imager	An automated device that is typically mounted on the gantry of a linear accelerator and intended to produce digital images of x-rayed anatomical landmarks to guide radiation treatment (e.g., tracking/targeting tumours). The device may be a digital imaging panel (e.g., of silicon) on robotic arms; it may also have an x-ray source to generate higher quality images.	**Class C**

64	Real-time position management respiratory gating system, optical/Respiratory gating system, radiation procedure	An assembly of electronic devices intended to track the respiratory pattern of a patient by means of optical technology to correlate tumour position with the respiratory cycle during radiation treatment planning, radiotherapy, computed tomography (CT) imaging, or other radiation procedures. It provides real-time position management (RPM) and involves optical-based tracking (e.g., video, infrared, laser) of the respiratory cycle to enable irradiation control during the procedure. It may include a tracking camera connected to a dedicated personal computer workstation and a reflective chest wall/abdominal marker.	**Class C**
65	Robotic Guidance system for image-Guided procedures	It is an accessory to an imaging system (CT, CT-PET) intended for the spatial positioning and orientation of an instrument guide. The device is not intended to make any contact with the patient.	**Class B**
66	Scalp cooling system, hair loss	An assembly of electrically-powered devices intended to reduce scalp hair loss associated with intravenous chemotherapy treatment by cooling the scalp to cause vasoconstriction and reduction of chemotherapy drug uptake by the follicular cells. An insulating cap (e.g., neoprene) may be worn over the cooling cap to secure it and prevent condensation.	**Class B**
67	Stereotactic radiosurgery system for central nervous system (CNS)	A set of devices intended to use very precise beams of gamma rays to treat an area of disease (lesion) or growth (tumour), especially in the brain, upper spine and in certain cases, vascular abnormalities.	**Class D**
68	Teletherapy radionuclide system table, powered	A device that is a component of a teletherapy radionuclide system (commonly known as a cobalt therapy machine) specifically intended to position and support a patient during treatments administered using a therapeutic radionuclide teletherapy system (e.g., a Cobalt-60 teletherapy system). It can be a stationary or mobile unit, or incorporated as an integral component of a radionuclide teletherapy system or gantry configuration.	**Class B**
69	Teletherapy radionuclide system, conventional/Cobalt therapy machine	A stationary assembly of devices intended to deliver a therapeutic radiation dose to an anatomical region from a single external radiation beam produced by a radionuclide source, typically to treat malignant tumours; it does not provide image-guided radiation therapy (IGRT) functionality during treatment delivery.	**Class C**
70	Telethermographic system	An electrically powered device intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body.	**Class A**

71	Therapeutic oncological/gynaecological ultrasound system (High intensity focused ultrasound (HIFU) ablation system)	An assembly of electrically-powered devices intended to treat solid tumours of hard (bone) and/or soft tissue [e.g., liver, kidney, breast, prostate] and/or gynaecological disorders (e.g., uterine fibroid, adenomyosis, etc.) through noninvasive or non-surgically invasive localized application of high intensity focused ultrasound (HIFU) or high intensity therapeutic ultrasound (HITU) intended to gradually denature/ablate tissue lesions.	**Class C**
72	Tumour-therapy radio-frequency hyperthermia system	A mains electricity (AC-powered) device assembly intended for controlled heating (i.e., temperatures around 43° Celsius) of the body using radio-frequency (RF) energy, for the treatment of malignant or benign tumours, or other disease conditions; it is not intended for direct tissue ablation. It is intended for both whole-body and localized heating of tissues/organs.	**Class C**
73	Tumour-therapy radio-frequency hyperthermia system applicator, intracorporeal	A component of a radio-frequency (RF) hyperthermia system intended to be placed in the body (either manually or endoscopically) to deliver RF energy to produce a systemic or local heating effect for the treatment of malignant or benign tumours, or other disease conditions. It is also referred to as an interstitial applicator or probe. This is a single use device.	**Class C**
74	Ultrasonic hyperthermia system/Ultrasonic ablation system	An assembly of devices intended to produce and control the delivery of high heat (i.e., temperatures greater than 43 deg Celsius) to the body using ultrasonic energy for the intracorporeal or extracorporeal treatment of malignant or benign tumours, or other disease conditions. It is not intended for physiotherapy applications.	**Class C**
75	Ultrasound hyperthermia system transducer, extracorporeal	An ultrasound (US) transducer assembly that is a component of an ultrasound hyperthermia system intended to induce systemic or local body heating of sufficient magnitude to create a targeted therapeutic effect. It is mounted within the gantry or housing of the hyperthermia system or mounted on a floor, wall, or ceiling suspension that allows the operator to position the transducer assembly external to the patient during treatment.	**Class C**
76	Ultraviolet Extracorporeal Photopheresis system	An assembly of devices intended for extracorporeal photoimmunetherapy to treat immune disorders, especially cutaneous T-cell lymphoma (CTCL). It irradiates the leukocyte-rich fraction of peripheral blood by UVA radiation extracorporeally and returns back the treated and untreated blood to the patient. This system may or may not use a UV-active drug (either ingested by patient or injected into the leukocyte-rich fraction of the extracted peripheral blood)	**Class C**

77	X-ray system tube	A replaceable component of a medical or dental diagnostic, or therapeutic x-ray system consisting of a tube (a glass envelope enclosing a filament, anode, cathode under vacuum, and an interface for an electrical connection) intended to convert an input of electrical energy into an output of x-ray energy. It is the x-ray system component that provides a supply of electrons which are free to move, a means of getting the electrons to travel at high-speed, and providing a force which will cause them to suddenly change direction which results in x-ray production. Included are designs referred to as cold-cathode gas discharge tubes, fixed anode tubes, rotating anode tubes, quick change tubes.	**Class B**