国家食品药品监督管理总局令

Order of the State Food and Drug Administration

No. 15

The rules for classification of medical devices, which were deliberated and adopted at the executive meeting of the State Food and Drug Administration on June 3, 2015, are hereby promulgated, and shall come into force as of January 1, 2016.

Director Jingquan Bi

July 14, 2015

CLASSIFICATION RULES OF MEDICAL DEVICES

Article 1 In order to standardize the classification of medical devices, these rules are formulated in accordance with "The Regulations On The Supervision And Administration Of Medical Devices".

Article 2 The rules are used to guide the development of medical device classification catalogue and the determination of new management category of medical devices.

Article 3 The meanings of the relevant terms in these rules are as follows:

(1) Intended Use

It refers to the effect that should be achieved by using medical devices as stated in the product instructions, labels or promotional materials.

(2) Non-Active Medical Device

Medical device that does not rely on electric energy or other energy sources, but can perform their functions through the energy generated by human body or gravity.

(3) Active Medical Device

Medical device that relies on electrical energy or other energy sources, rather than directly generated by human body or gravity, to perform its function.

(4) Invasive Device

Medical device that invades the human body completely or partially through the body surface and contact the tissues, blood circulation system, central nervous system and other parts with the aid of surgery, including the equipment used in interventional surgery, disposable sterile surgical instruments and temporary or short-term instruments left in the human body. Invasive instruments in this regulation do not include re-use surgical instruments

(5) Reusable Surgical Instrument

They are non-active devices, used for cutting, cutting, drilling, sawing, grasping, scraping, forceps, drawing, clamping and other processes in surgeries. They do not connect any active medical devices and can be reused after certain process.

(6) Implantable Device

Medical device that is completely or partially entered into the human body or cavity (mouth) with the aid of surgery, or are used to replace the human epithelial surface or eye surface, and remain in the human body for more than 30 days (inclusive) or absorbed by the human body after the operation.

(7) Patient-Contact Device

Medical device that directly or indirectly contacts patients or can enter patients.

(8) Usage Time

1) Continuous usage time: time that a medical device is continuously in use according to the intended use;
2) Temporary use: The continuous use time of medical device according to the intended use is **within 24 hours**.
3) Short-term use: The continuous use time of medical device according to the intended use is **more than 24 hours (including) and less than 30 days**.
4) Long-term use: The continuous use time of medical device according to the intended use is **more than 30 days**.

(9) Skin

Undamaged skin surface.

(10) Cavity (Orifice)

Oral cavity, nasal cavity, esophagus, external auditory canal, rectum, vagina, urethra and other natural cavity and permanent artificial openings.

(11) Trauma

The damage of tissue structure integrity or dysfunction caused by various injury factors on human body

(12) Tissue

Tissue in the body, including bone, dental pulp or dentin, excluding the blood circulation system and central nervous system

(13) Blood circulation system

Blood vessels (except capillaries) and heart

(14) Central nervous system

Brain and spinal cord

(15) Stand-alone software

The software that has one or more medical purposes and can complete its intended use without medical device hardware, and runs on the general computing platform

(16) Medical devices with measurement and testing function

Medical devices used to determine physiological, pathological, anatomical parameters, or quantitative determination of energy or substances in and out of the human body, its measurement results need to be accurate and quantitative, and the accuracy of the results will have a significant impact on the health and safety of patients.

(17) Chronic wound

Long-term wounds without various causes, such as venous ulcer, arterial ulcer, diabetic ulcer, traumatic ulcer, pressure ulcer, etc.

Article 4 According to the risk levels of medical devices from low to high, the management categories are divided into Class I, Class II and Class III.

The risk level of medical devices shall be comprehensively determined according to the intended use of the medical devices through such factors as structural characteristics, usage forms, usage status, whether it contacts human body.

Article 5 According to the factors affecting the risk degree of medical devices, medical devices can be divided into the following categories:

(1) According to the different structural characteristics, it can be divided into non-active medical devices and active medical devices.

(2) According to the contact with human body, it can be divided into contact human body device and non-contact human body device.

(3) According to different structural characteristics and whether it contacts human body, the usage forms of medical devices include:

Non-active contact devices: liquid delivery devices, blood and body fluid change devices, medical dressings, invasive devices, reusable surgical instruments, implantable devices, contraceptive and family planning devices, and other non-active contact human devices.

Non-active non-contact human body equipment: nursing equipment, medical equipment cleaning and disinfection equipment, other non-active non-contact human body equipment.

Active contact devices: energy therapy devices, diagnostic monitoring devices, liquid delivery devices, ionizing radiation devices, implantable devices, and other active contact devices.

Active non-contact human equipment: clinical laboratory equipment, independent software, medical device disinfection and sterilization equipment, other active non-contact human equipment

(4) According to different structural features, contact with human body and usage form, the usage status of medical device or its influence includes the following situations:

Non-active contact with human instruments: according to the usage time limit, it can be divided into temporary use, short-term use and long-term use; the parts contacting human body can be divided into skin or cavity (mouth), trauma or tissue, blood circulation system or central nervous system.

Non-active non-contact human body equipment: according to the degree of impact on medical effect, it can be divided into basic no impact, slight impact and important impact.

Active contact with human instruments: according to the degree of damage that may be caused after losing control, it can be divided into slight injury, moderate injury and severe injury.

Active non-contact human equipment: according to the degree of influence on medical effect, it can be divided into basic no effect, slight influence and important influence.

Article 6 The classification of medical devices shall be determined according to the Classification Decision Table of Medical Devices (see appendix). In case of any of the following circumstances, the classification shall be made in combination with the following principles:

(1) If two or more classifications are applicable to the same medical device, the classification with the highest risk level shall be adopted. For the medical device package composed of multiple medical devices, the classification shall be consistent with the medical device with the highest risk degree in the package.

(2) For the medical devices that can be used as accessories, their classification should comprehensively consider the impact of the accessories on the safety and effectiveness of the main medical devices. If the accessories have an important impact on the supporting main medical devices, the classification of the accessories should not be lower than that of the supporting main medical devices.

(3) The classification of medical devices that monitor or affect the main functions of medical devices shall be consistent with the classification of medical devices monitored and affected.

(4) The drug-device combination products with the main function of medical devices shall be managed according to Class IIII medical devices.

(5) Medical devices that can be absorbed by human body shall be managed according to Class III medical device.

(6) Active device with patient contact, that has important impact on medical effect, shall be managed according to Class III medical device.

(7) Medical dressings shall be managed as Class III medical device in case of the following situations: expected to have the function of preventing tissue or organ adhesion, as artificial skin, contact with the wound surface with deep or below dermal tissue damage, used for chronic wound, or can be completely or partially absorbed by the human body.

(8) The classification of medical devices provided in sterile form shall not be lower than Class II.

(9) Orthopedic instruments that can actively exert continuous force on the human body and dynamically adjust the fixed position of the limbs by pulling, stretching, twisting, pressing and bending (excluding the medical devices that only have the function of fixation and support, and also do not include the medical devices for temporary orthopedics in surgery or those for limb orthopedics after surgery or other treatments) The classification should not be lower than Class II.

(10) The classification of medical devices with measurement and test function shall not be lower than Class II.

(11) If the intended use of medical device is to explicitly use for the treatment of a certain disease, its classification should not be lower than Class II.

(12) The non-active reusable surgical instruments used for clipping, cutting tissue or taking stones under endoscope shall be managed according to Class II medical device.

Article 7 In Vitro diagnostic reagent products have a different classification.

Article 8 State Food and Drug Administration timely analyzes and evaluates the risk changes of medical devices, and adjusts the classification catalogue of medical devices according to the production, operation and usage of medical device.

Article 9 State Food and Drug administration may organize a medical device classification expert committee to formulate and adjust the medical device classification catalogue.

Article 10 These rules shall come into force as of January 1, 2016. The classification rules for medical devices (Order No. 15 of the former State Drug Administration) promulgated on April 5, 2000 shall be repealed at the same time

Appendix Decision Table for Medical Device Classification

APPENDIX

Decision Table for Medical Device Classification

Patient Contact Device										
Non-Active Device	Application / Usage		Temporary Contact			Short Term Contact			Long Term Contact		
			Skin/cavity (mouth)	Puncture / Tissue	Blood circulation /Central	Skin/cavity (mouth)	Puncture / Tissue	Blood circulation /Central	Skin/cavity (mouth)	Puncture / Tissue	Blood circulation /Central
	1	Fluid delivery	II	II	III	II	II	III	II	III	III
	2	Device that changes blood or body fluid	–	–	III	–	–	III	–	–	III
	3	Medical medium	I	II	II	I	II	II	–	III	III
	4	Invasive Device	I	II	III	II	II	III	–	–	–
	5	Re-usable surgical device	I	I	II	–	–	–	–	–	–
	6	Implantable device	–	–	–	–	–	–	III	III	III
	7	Contraceptive and family planning device (Not including in reusable surgical instruments)	II	II	III	II	III	III	III	III	III
	8	Other device	I	II	III	II	II	III	II	III	III

Decision Table for Medical Device Classification

	Application / Usage		Slight Injury	Medium Injury	Severe Injury
Active Device	1	Energy treatment	II	II	III
	2	Diagnostic monitoring	II	II	III
	3	Fluid delivery	II	II	III
	4	Radiation	II	II	III
	5	Implant	III	III	III
	6	Other active device	II	II	III

Non-Patient-Contact Medical Device					
	Usage Status / Usage Form		Basically No Impact	Minor Impact	Important Impact
Non-Active Device	1	Nursing/recovery device	I	II	–
	2	Medical device cleaning sterilization device	–	II	III
	3	Other non-active device	I	II	III
Active Device	1	Clinical testing instruments (IVD instruments)	I	II	III
	2	Stand-alone software	–	II	III
	3	Medical device cleaning sterilization device	–	II	III
	4	Other active device	I	II	III