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Provisions for Medical Device Classification

(Order No. 15 of SDA)

The Provisions for Medical Device Classification were passed by the State Drug Administration at the administration affairs meeting on February 17 of 2000, are hereby promulgated and shall go into effect as of April 10, 2000.
April 5, 2000

Provisions for Medical Device Classification

Article1 The Provisions are stipulated in accordance with the Regulation on Supervision and Administration of Medical Device to standardize the classification of medical devices.

Article2 "Medical devices" refer to those instruments, equipment, tools, materials and other objects, including the software attached to them, that are designed to be used either independently or in combination on human body. These devices are used for:
1.Prevention, diagnosis, treatment, monitoring or remission of diseases;
2. Diagnosis, treatment, monitoring, remission or compensation of injury or physical disability;
3.Research, replacement or adjustment of anatomical or physiological process;
4. Control of pregnancy.
Basically, the effect of these devices on human body is not achieved through means of pharmacology, immunology or metabolism; though they might be resorted to in order to bring about certain supplementary effect.

Article3 The Provisions are meant to direct the formulation of The Category of Medical Device Classification as well as to determine the classes of newly registered products.

Article 4 The classification of medical devices should be determined by a combined judgement on three respects: its structural characteristics, form of operation as well as conditions for use.
Specifically, their classification can be based on Criteria for Medical Device Classification (see appendix).

Article 5 Guidelines for Medical Device Classification
1. The structural characteristics of medical devices
According to their respective structural characteristics, medical devices are divided into active and passive devices.
2. The forms of operation of medical devices
Medical devices are designated into different forms of operation in accordance with their intended purposes.
1) Passive devices in terms of their form of operation can be classified as device used for transportation and storage of pharmaceutical liquid, device for alteration of blood, body fluids, medical dressing, surgical instruments; reusable surgical instruments, disposable aseptic device, implantable device, device for contraception and birth control, device for sterilization and cleaning, patient care device, in vitro diagnostic reagent, as well as other passive contacting device or passive supplementary device.
2) Active devices in terms of their form of operation can be classified as device for treatment through energy, diagnostic monitoring, body fluids transportation and ionized radiation, laboratory instruments and medical sterilizer; as well as other active contacting device or active supplementary device.
3. The conditions for use of medical devices:

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Medical devices may be divided into contacting or inserted devices and non-contacting devices based on their conditions for use, which include the possible injuries they might entail as well as their impact on the medical treatment.

1) Contacting or inserted devices

a. Term of use: temporary use, short - term use, long-term use;

b. Particular parts of the human body being contacted:

skin, cavity and tract; trauma or body tissue; blood circulation system or central nervous system;

c. The degree of injuries caused by malfunction of active devices:

minor injuries, injuries, serious injuries.

2) Non-contacting Devices

The impact these devices have on treatment ranges from: basically no impact, indirect impact, substantial impact.

Article 6 Principles for Medical Device Classification

1. The classification of medical devices should be conducted in accordance with The Criteria for Medical Device Classification.

2. The criteria for medical device classification are based on the intended purpose and the function of a medical device. To the same product, if the intended purpose or form of operation be different, its class shall be determined respectively.

3. For the medical device to be used in combination with another, the classification of each should then be dealt with separately. Accessories to medical devices should be classified independently from the master device respecting its own conditions.

4. For the medical device to be used on several parts of the human body, the classification should be determined on the basis of the risks involved in its intended purposes and form of operation.

5. Software that controls the functions of the medical device should be designated to the same class of its associated medical device.

6. If one medical device pertains to two classes at the same time, the higher one is adopted.

7. Those products that are designed to monitor or affect the major functions of a medical device should be designated to the same class of the device being monitored or affected.

8. The State Drug Administration shall readjust as it sees fit the classification of certain medical devices that call for special administration.

Article 7 The State Drug Administration is competent authority take charge of the classification of medical devices. In case a medical device fails to be designated according to The Category of Medical Device Classification, its classification then should be based on The Regulation for Medical Device Classification at the discretion of the provincial drug administration, the result of which should be submitted to the State Drug Administration for approval.

Article 8 The terms used in the provisions are defined as follows:

1. Intended purpose: the desired effect of a medical device that is illustrated in its product specification, label or materials for publicity.

2. Risk: the possible injuries that may be caused by the medical device and the seriousness of the injury.

3.Term of use:

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1) Temporary Use: the intended term for consecutive use of the device is within 24 hours;
2) Short-term Use: the intended term for consecutive use of the device ranges from 24 hours to 30 days;
3) Long-term Use: the intended term for consecutive use of the device is more than 30 days.
4) Term for consecutive use: the actual working time of a device without any stop in accordance with its intended purpose.
4. Parts being operated upon and the device:
1) Non-contacting devices: devices that do not directly or indirectly contact the body of a patient;
2) Surface contacting devices: including devices contacting the following parts of the human body:
a. skin: devices that only contact the surface of the unwounded skin;
b. mucous membrane: devices that contact the mucous membrane;
c. wounded surface: devices that contact the wounded area or the surface of other injured areas.
3) Devices for surgical insertion: devices that are entirely or partly inserted into the body through the surface of body by surgery contacting the following parts of the human body:
a. blood vessel: inserted devices contacting a point on a blood vessel or as a channel to the blood vessel system.
b. tissue/bone/dentinum: devices and materials that are inserted into the tissue, bones as well as endodontium/dentinum system.
c. blood circulation: devices that contact the blood circulation system.
5.Implantables: devices that are entirely or partly inserted into the cavity or tract of the human body by surgery. These devices either remain in the body over a long period of time, or partly remain in the body for at least 30 days.
6. Active device: any medical device that operates on electric power or other forms of energy excluding those directly generated by human body or gravity.
7. Reusable surgical instruments: devices that are used to conduct such procedures during a surgery as excision, boring, sawing, clutching, scraping, clipping, drawing and clamping without having to resort to any active device and that can be reused after certain treatment.
8.Central Circulation System: referring to a number of vessels of the blood circulation system including pulmonary artery, aorta, coronary artery, carotid artery, cerebral artery, cardiac vena, upper cavity vena, and lower cavity vena.
9. Central Nervous System: referring to cerebrum, meninx and medulla spinalis.

Article 9 The State Drug Administration is responsible for interpretation of the provisions.
Article 10 The Provisions shall go into effect as of April 10, 2000.