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Classification of Medical Devices to Safeguard Public Health and Safety

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Introduction

Safety can only be regarded as relative in nature. All medical devices have a particular degree of risk which could lead to problems in specific conditions. Therefore, the level of regulatory control applied to a medical device should take account of the risks and benefits related to its use. For the sake of preventing unnecessary burden on manufacturers or regulators as well as offering local consumers the access to medical devices of latest technology, medical devices are divided by the rules of classification into different classes. Each class is subjected to a level of regulatory control which is proportional to the risk level associated.

Objectives

- (1) To classify medical devices based on their risk to patients, users and other persons;
- (2) To adjust the level of regulatory control according to the risks and benefits associated with use of the medical device;
- (3) To develop a globally harmonized classification system for manufacturers and Regulatory Authorities.

Methodology

Medical devices are separated into four classes. Class IV Medical Devices carry the highest risk, while Class I Medical Devices carry the lowest risk. The risk level generally depends on the intended use and design of a medical device. The actual device classification may also be affected by one or several of the following factors, for example, the duration of device in contact with the body, the degree of invasiveness, whether the device delivers medicines or energy to the patient, whether they are intended to have a biological effect on the patient and local versus systematic effects (e.g. conventional versus absorbable sutures).

As an illustrative example, angioplasty balloon catheters and related guide wires are classified as Class IV. The rule for determination is that they are surgically invasive devices intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body.

Result

The classification system of medical devices consists of four classes, with increasing risk level of devices from Class I to IV. Higher level of regulatory control should be applied on medical devices of higher risk to control their supply and use, so as to safeguard the health and safety of patients, users and other persons.