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May 4, 1998

To: Medical Devices Stakeholders

Subject: Guidance for the risk based classification system (Draft)

The proposed *Medical Devices Regulations* set out the requirements governing the sale, importation and advertisement of medical devices. The goal of the Regulations is to ensure that medical devices distributed in Canada are safe, effective, and meet quality standards. It is the intention of the Therapeutic Products Programme to have these proposed Regulations published in Canada Gazette II in May 1998 and begin implementation on July 1, 1998.

This draft document, titled Guidance for the risk based classification system, sets out the Programme's guidance for Industry on the subject. It is being provided now in a draft format so that interested stakeholders can comment and participate in its development.

The goal of this document is to help manufacturers, importers and distributors understand the risk based classification system for medical devices other than *in vitro* diagnostic devices as described in Part I of Schedule I of the *Medical Devices Regulations* and to provide guidance on how to classify their devices.

To comment or to get more information on the risk based classification system for medical devices other than *in vitro* diagnostic devices please contact by May 15, 1998 the following:

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Thank you for providing your
comments.

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Attachments

Therapeutic Products Programme

OUR MISSION: To ensure that the drugs, medical devices, and other therapeutic products available in Canada are safe, effective and of high quality.

Programme des produits thérapeutiques

NOTRE MISSION: Faire en sorte que les médicaments, les matériels médicaux et les autres produits thérapeutiques disponibles au Canada soient sûrs, efficaces et de haute qualité.

DRAFT

Therapeutic Products Programme
GUIDANCE DOCUMENT

Guidance for the Risk-based Classification System

Date Prepared / Draft Number	May 4, 1998 (md_risk5.wpd)
Supersedes	April 8, 1998
Date Approved by Responsible Authority	
Date Transmitted for External Consultation	
Document Number	GD006/RevDR-MDB

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1 Introduction

1.1 Purpose

The purpose of this document is to act as an interpretative document to guide the user through the application of the risk classification rules of the *Medical Devices Regulations* for medical devices other than *in vitro* diagnostic devices.

1.2 Background

A risk classification scheme has been developed to categorize medical devices according to their potential risk. The degree of regulation imposed on any device is proportional to its risk. The classification rules were designed to be straight forward and user friendly and the following indicators of risk were used to create the rules: degree of invasiveness, duration of contact, body system affected, and local versus systemic effects.

It is acknowledged that this or any rule system has limitations and cannot accommodate all devices. There may be cases where either a device cannot be classified because of an unusual characteristic or where the resulting classification is not optimum given known hazards associated with the use of the device. In these cases the device may be listed on the table to Rule 16 of the *Medical Devices Regulations*.

The Canadian device classification rules were developed so that they were harmonized with the European Union's device classification rules and the device classifications of the United States.

1.3 Scope

This document provides guidance for only the non-*in vitro* diagnostic devices (IVDD) rules. Classification rules for IVDDs are discussed in the guidance document "Guidance for the risk based classification system of *in vitro* diagnostic devices, GD007/RevDR-MDB".

1.4 Acknowledgement

The rules developed for the Canadian classification system borrow significantly from those which appear in the European Union's Council Directive 93/42/EEC. Many of the rules and interpretations of terms are either the same as, or similar to, those proposed by the European Union in the supporting documentation to the Council Directive.

1.5 Definitions

The following key terms are found within the risk classification rules. Their definitions are the same as those given in the *Medical Devices Regulations*. Terms that appear in bold in the text of this document indicates that they have been defined in this section.

"ACTIVE DEVICE"

Means a medical device that depends for its operation on a source of energy other than the energy

generated by the human body or gravity. A medical device that transmits or withdraws energy or a substance to or from a patient without substantially altering the energy or the substance is not an active device.

“ACTIVE DIAGNOSTIC DEVICE”

Means an active device that, whether used alone or in combination with another medical device, is intended to supply information for the purpose of detecting, monitoring or treating a physiological condition, state of health, illness or congenital deformity.

“ACTIVE THERAPEUTIC DEVICE”

Means an active device that, whether used alone or in combination with another medical device, is intended to support, modify, replace or restore a biological function or structure for the purpose of treating or mitigating an illness or injury or a symptom of an illness or injury.

“BODY ORIFICE”

Means a natural opening or a permanent artificial opening in the body, such as a stoma.

“CENTRAL CARDIOVASCULAR SYSTEM”

Means the heart, pericardium, pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, common carotid arteries, cerebral arteries, brachycephalic artery, aorta, inferior and superior vena cava, renal arteries, iliac arteries and femoral arteries,

“CENTRAL NERVOUS SYSTEM”

Means the brain, meninges, spinal cord and cerebrospinal fluid

“CLOSED-LOOP SYSTEM”

In respect of a medical device, means a system that enables the device to sense, interpret and treat a medical condition without human intervention.

“DENTAL MATERIAL”

Means a medical device that is to be inserted into the pulp cavity of a tooth or attached only to the enamel or dentin of a tooth. It does not include a surgical or dental instrument.

“INVASIVE DEVICE”

Means a medical device that is intended to come into contact with the surface of the eye or penetrate the body, either through a BODY ORIFICE or through the body surface.

“MEDICAL DEVICE”

For the purpose of these regulations a “medical device” is defined as it appears in the *Food and Drugs Act* with, however, the exclusion of veterinary products.

.....an article, instrument, apparatus or contrivance, including a component, part or accessory of one, that is manufactured, sold or represented for use in:

- a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in a human being;
- b) the restoration, correction or modification of a body function or the body structure of a human being;
- c) the diagnosis of pregnancy in a human being; or
- d) the care of a human being during pregnancy and at and after the birth of a child, including the care of the child.

It also includes a contraceptive device but does not include a drug.

“SURGICAL OR DENTAL INSTRUMENT”

Means a reusable MEDICAL DEVICE that is intended for surgical or dental use, including cutting, drilling, sawing, scraping, clamping, hammering, puncturing, dilating, retracting or clipping without connection to a MEDICAL DEVICE.

“SURGICALLY INVASIVE DEVICE”

Means an INVASIVE DEVICE that is intended to enter the body through an artificially created opening that provides access to body structure and fluids.

2 How to Carry Out the Classification of A Medial Device

The rules for medical devices other than *in vitro* diagnostic devices can be grouped into four sets characterized as:

- Invasive Devices**
- Non-invasive Devices**
- Active Devices**
- Special Rules**

The first step in determining the risk classification of a device is to check Special Rules 13 to 15 and the Table to Rule 16. If the device in question is not described by one of these Special Rules then it should be determined if the device is either invasive, non-invasive or active. A device could be described as both non-invasive and active or invasive and active and it is not unusual for more than one rule to apply to any given device. The final classification, however, will be determined by the rule which assigns the highest risk classification.

It must be stressed that it is the “intended use” of the device that ultimately determines the device’s classification. For example, an ear oximeter or any oximeter intended only for sampling percent oxygen saturation is Class II by Rule 10(1), while an intracardiac oximeter is Class IV by rule 1(2) and a pulse oximeter recommended for use in the operating and recovery room for continuous monitoring of arterial oxygen saturation is Class III by Rule 10(2). Three oximeters - three different classifications. Another example would be an ECG machine intended only to be used in a doctor’s office for routine check-ups versus an ECG machine intended to be used in critical care settings. The former would be Class II by Rule 10(1) and the latter Class III by Rule 10(2).

2.1 Time

The Canadian rule system only distinguishes between devices whose use is considered to be “long term” or not. Long term use, implies “continuous use” for a period of 30 days or greater. Continuous use is understood to be uninterrupted use for the intended purpose.

2.2 Invasiveness

Any device which, in whole or in part, penetrates inside the body, either through a **BODY ORIFICE** or through the surface of the body is an **INVASIVE DEVICE**. A **BODY ORIFICE** may be either a natural body orifice or a permanent artificial opening. A **SURGICALLY INVASIVE DEVICE** always implies that it enters through an artificially created opening. This can be a large opening, such as a surgical incision, or it can be a pinprick opening created by a needle. Therefore, surgical gloves, and needles used with syringes, are surgically invasive.

There are two exceptions to this interpretation:

- A surgically created stoma used in colostomy and ileostomy is considered, for classification purposes, to be a natural **BODY ORIFICE**. Therefore, devices introduced into such a stoma are not surgically invasive. In contrast, a surgically created opening, to allow access to the circulatory system, should not be considered to be such a “natural body orifice.” Devices, introduced into such an opening, are surgically invasive.
- A device that administers energy to the body should not be considered as invasive if only energy penetrates the body and not the device itself. Energy, as such, is not a device and therefore, it cannot be classified. Only the device generating the energy can be classified. However, if a device administers a substance, whether this substance is a medicine or a **MEDICAL DEVICE**, such substances must be assessed in their own right (e.g., substances administered by a jet injector).

2.3 Active Devices

The definition of “active device” contains the sentence, “devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant

change, are not considered to be active devices.” For example, an electrode is not considered to be an active MEDICAL DEVICE. Rather, an electrode is attached to an active device, and is classified accordingly.

MEDICAL DEVICES using pre-stored gases and/or vacuum as a power source are regarded as active devices. For example, gas mixers with anaesthesia machines and gas powered suction pumps are considered active medical devices. Any device whose function depends on gravity or a force provided by a human is not considered an active device. For example, intravenous administration sets rely on gravity for drainage and are not active devices. Likewise a syringe which relies on a human hand to depress the plunger is not an active medical device.

Radioactive sources that are intended to deliver ionizing radiation are also considered to be active medical devices.

2.4 Application of the Rules

- a) If a device can be classified according to several rules, then the highest possible class applies.
- b) Classification must be consistent with the claims that appear on the labelling or that are contained within other information provided with the device such as brochures, operating manuals and the directions for use.
- c) If the intended use of the device is not clearly specified in the information accompanying the device, then the intended use will be deemed to be that accepted in general medical practice.
- d) Multi-application equipment such as laser printers and identification cameras, which may be used in combination with MEDICAL DEVICES, are not MEDICAL DEVICES, unless their manufacturer places them on the market with the specific restriction that they are intended to be used only with MEDICAL DEVICES.
- e) The manufacturer of a MEDICAL DEVICE consisting of component parts has the option of classifying the device as a system, or classifying each of the parts separately. For example, a drainage device will have an invasive tube and a non-invasive collection device. It is up to the manufacturer to determine whether he will classify the drainage system as a whole, or classify the components.

2.5 Device/Drug Combination and Classification Issues

The interpretation and approach of the Therapeutic Products Programme to the issue of Device/Drug Combination products is given in a separate Policy document, “Drug/Medical

Device Combination Products.”

2.6 Dispute Resolution

Should there be a disagreement between the device manufacturer and the Therapeutic Products Programme over the classification of a MEDICAL DEVICE, there will be a mechanism whereby the manufacturer can appeal the Programme’s decision. This mechanism is currently being developed.

2.7 How to use the Rule and the Decision Tree

The manufacturer must take into consideration **all the rules** in order to establish the proper classification for his device. It is quite conceivable, in the case of an active device, that one of the general rules, (invasive/noninvasive), that is not specific to active devices, nevertheless applies to such a device. **All device characteristics must be taken into account.**

3 EXPLANATION OF INDIVIDUAL RULES

This section begins with a reproduction of the rules as they are presented in the *Medical Devices Regulations*, followed by a graphical depiction of the rules.

Each rule is then individually addressed and examples given. It is the responsibility of the manufacturer to classify his “device” as it may have characteristics or intended purposes that would exclude it from the example given.

3.1 CLASSIFICATION RULES

Invasive Device Rules

Rule 1:

- (1) Subject to subrules (2) and (3), all **SURGICALLY INVASIVE DEVICES** are classified as Class II.
- (2) A **SURGICALLY INVASIVE DEVICE** that is intended to diagnose, monitor, control or correct a defect of the **CENTRAL CARDIOVASCULAR SYSTEM**, the **CENTRAL NERVOUS SYSTEM** or of a fetus *in utero*, is classified as Class IV
- (3) A **SURGICALLY INVASIVE DEVICE** that is intended to be absorbed by the body, or that is normally intended to remain in the body for a least 30 consecutive days, is classified as Class III.

Rule 2:

- (1) Subject to subrules (2) and (3), all **INVASIVE DEVICES** that penetrate the body through a

BODY ORIFICE or that comes into contact with the surface of the eye are classified as Class II.

- (2) A device described in subrule (1) that is intended to be placed in the oral or nasal cavities as far as the pharynx or in the ear canal up to the ear drum is classified as Class I.
- (3) A device described in subrule (1) that is normally intended to remain in the body or in contact with the surface of the eye for at least 30 consecutive days is classified as Class III.
- (4) A device described in subrule (1) that is intended to be represented as preventing the transmission of infectious agents during sexual activities or reducing the risk thereof is classified as Class III.

Rule 3:

Despite rules 1 and 2

- (a) All denture materials and orthodontic appliances, and their accessories, are classified as Class II; and
- (b) all **SURGICAL OR DENTAL INSTRUMENTS** are classified as Class I; and
- (c) all latex condoms are classified as Class II

Rule 4:

- (1) Subject to subrule (2), all non-**INVASIVE DEVICES** that are intended to come into contact with injured skin are classified as Class II.
- (2) A device described in subrule (1) that is intended to be used as a mechanical barrier, for compression or for absorption of exudations is classified as Class I.

Rule 5:

A non-**INVASIVE DEVICE** intended for channelling or storing gases, liquids, tissues or body fluids for the purpose of introduction into the body by means of infusion or other means of administration is classified as Class II.

Rule 6:

- (1) Subject to subrules (2) and (3), a non-**INVASIVE DEVICE** intended for modifying the biological or chemical composition of blood or other body fluids, or liquids, for the purpose of introduction into the body by means of infusion or other means of administration is classified as Class III.

- (2) A device described in subrule (1) whose characteristics are such that the modification process may introduce a foreign substance into the body that is potentially hazardous, taking into account the nature and quantity of the substance, is classified as Class IV.
- (3) A device described in subrule (1) whose modification is accomplished by centrifugation, gravity filtration or the exchange of gas or heat is classified as Class II.

Rule 7:

- (1) Subject to subrule (2), all other non-**INVASIVE DEVICES** are classified as Class I.
- (2) A device described in subrule (1) that is;
 - (a) intended to act as a calibrator, tester or quality control support to another medical, or
 - (b) to be connected to an active device that is classified as Class II, III or IV is classified as Class II.

Active Device Rules

Rule 8:

- (1) Subject to subrules (2) and (3), an **active device** intended to emit ionizing radiation, including any device or software intended to control or monitor such a device or directly influence its performance, is Classified as Class III.
- (2) A device described in subrule (1) that is intended to be used in radiographic mode is classified as Class II
- (3) Despite subrule (2), an active device that is intended to be used for mammographies is classified as Class III.

Rule 9:

- (1) Subject to subrules (2) and (3), an **ACTIVE THERAPEUTIC DEVICE**, including any dedicated software, intended to be used to administer or withdraw energy to or from the body is classified as Class II.
- (2) If the administration or withdrawal by a device described in subrule (1) is potentially hazardous, taking into account the nature of the administration or withdrawal, the intensity of the energy and the part of the body concerned, the device is classified as Class III.
- (3) A device described in subrule (2) that is intended to control the treatment of a patient's condition through a **closed loop system** is Class IV.

Rule 10:

- (1) Subject to subrule (2), an **ACTIVE DIAGNOSTIC DEVICE**, including any dedicated software, that supplies energy for the purpose of imaging or monitoring physiological processes is classified as Class II.
- (2) A device described in subrule (1) that is intended to be used to monitor, assess or diagnose disease, a disorder, an abnormal physical state, or pregnancy, where erroneous readings could result in immediate danger, is classified as Class III.

Rule 11:

- (1) Subject to subrules (2) and (3), an **active device**, including any dedicated software, intended to administer or withdraw drugs, body fluids or other substances to or from the body is classified as Class II.
- (2) If the administration or withdrawal by a device described in subrule (1) is potentially hazardous, taking into account the nature of the administration or withdrawal, the nature of the substance involved and the part of the body concerned, the device is classified as Class III.
- (3) A device described in subrule (2) that is intended to control the treatment of a patient's condition through a **closed loop system** is classified as Class IV.

Rule 12:

Any other active device is classified as Class I.

Special Rules

Rule 13:

A **MEDICAL DEVICE** that is intended to be used for:

- (a) disinfecting or sterilizing blood, tissues or organs that are intended for transfusion or transplantation is classified as Class IV; and
- (b) disinfecting or sterilizing a **MEDICAL DEVICE** is classified as Class II.

Rule 14:

- (1) Subject to subrule (2), any **MEDICAL DEVICE** manufactured from or incorporating non-viable or viable, animal or human tissue or their derivatives, or a product produced through the use of recombinant Deoxyribonucleic Acid (DNA) technology, is classified as Class IV.
- (2) A device described in subrule (1) that is only intended to come into contact with intact skin

is classified as Class I.

Rule 15:

Any MEDICAL DEVICE that is a material that is intended to be sold to a health care professional or dispenser for the specific purpose of configuration or arrangement into a mould or shape to meet the needs of an individual is classified in the class that applies to the finished MEDICAL DEVICE.

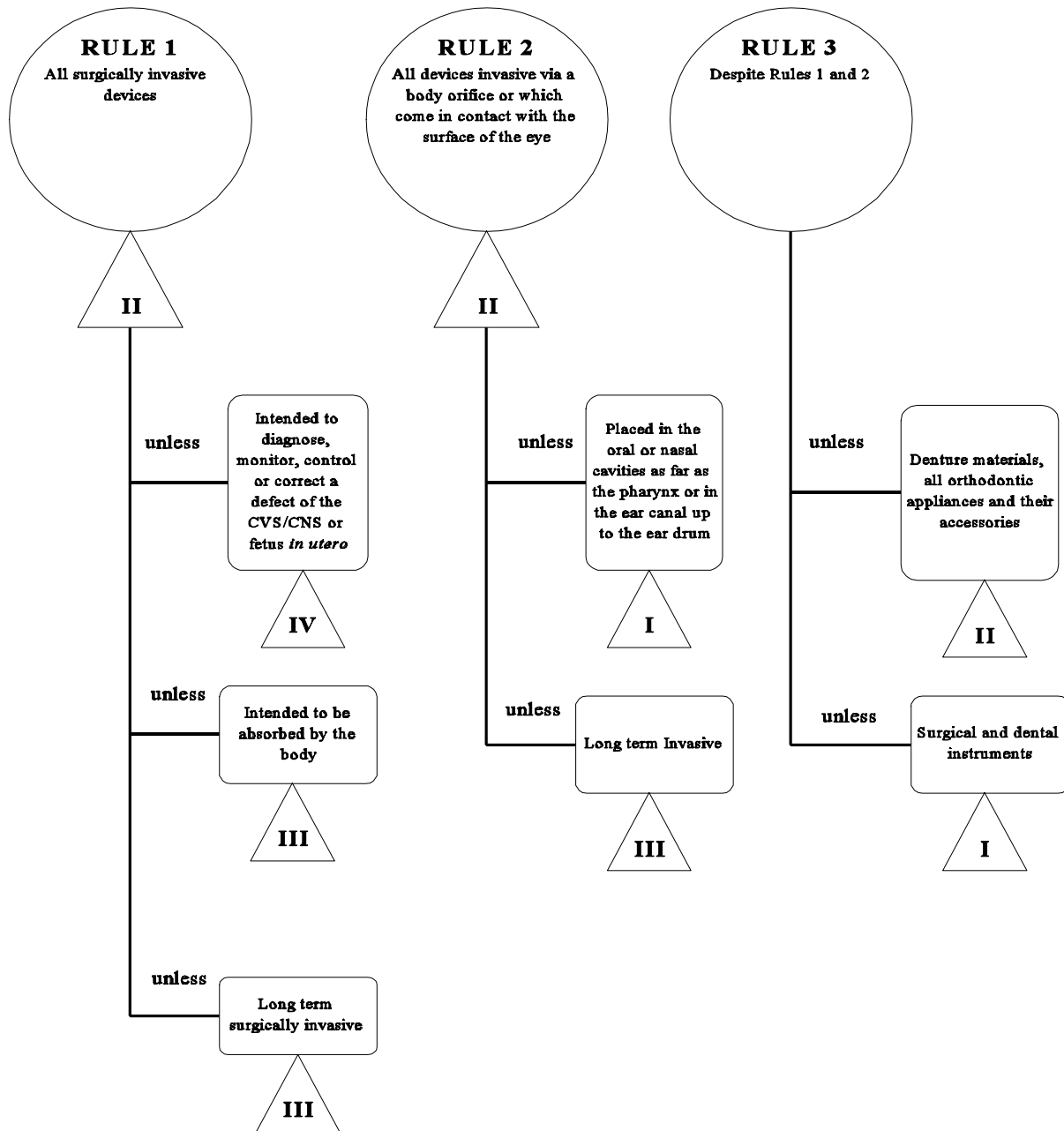
Rule 16:

Despite rules 1 to 15, a MEDICAL DEVICE set out in column 1 of an item of the table to this rule is classified as the class set out in column 2 of that item.

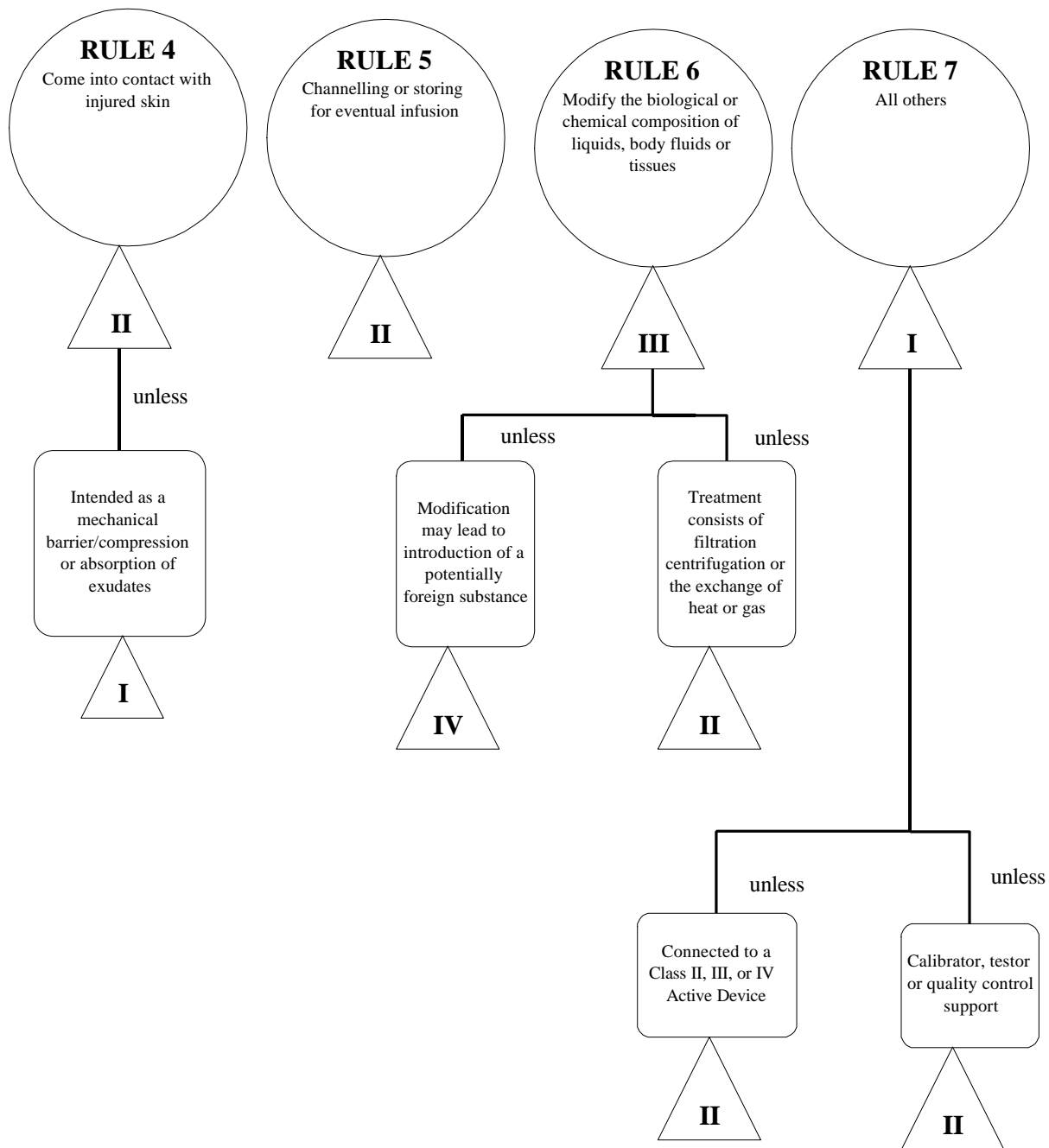
Item	Column 1 Medical Device	Column 2 Class
1	Breast Implants	IV
2	Tissue Expanders for breast reconstruction & augmentation	IV

3.2 Flow Diagrams

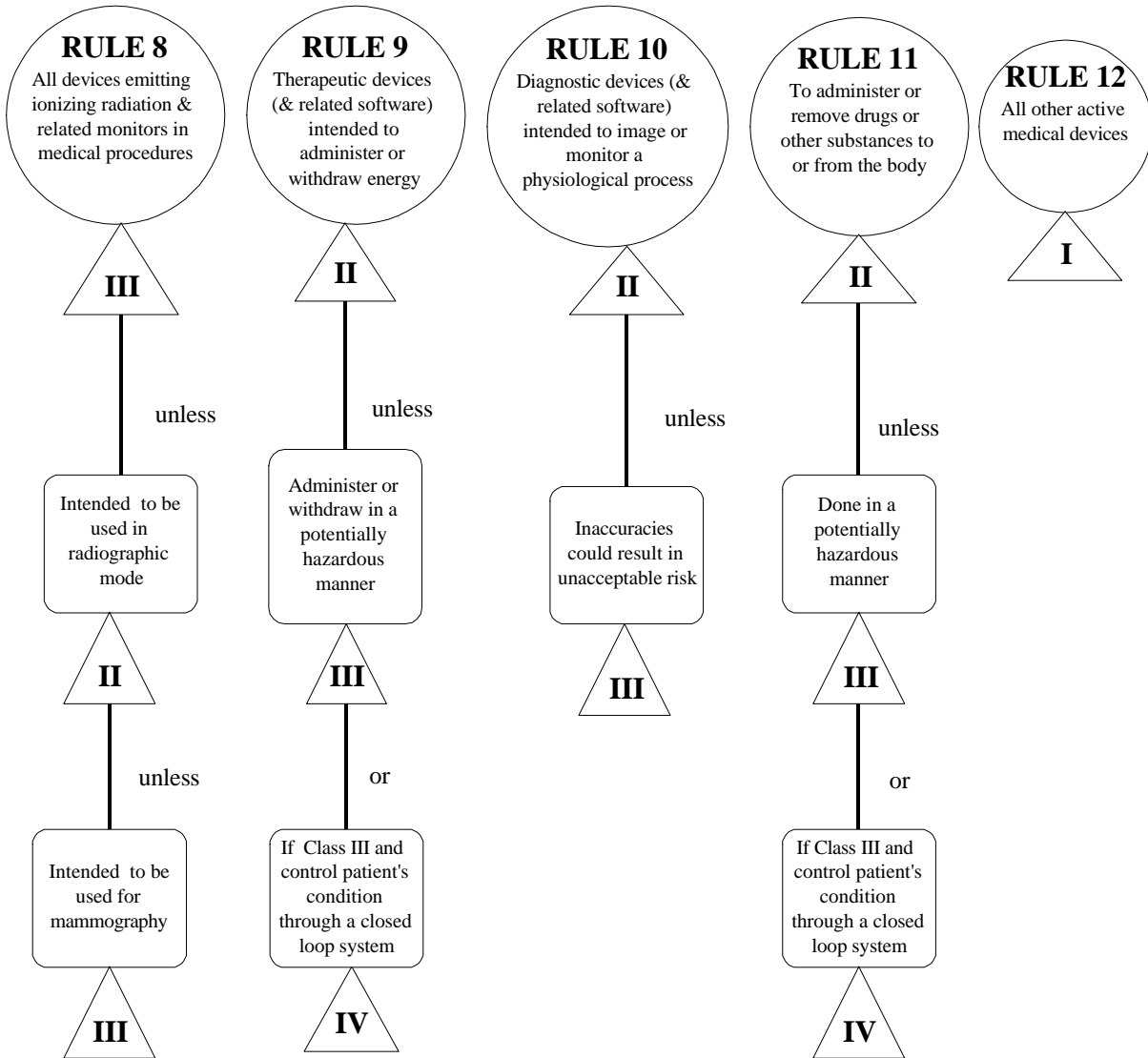
INVASIVE DEVICES



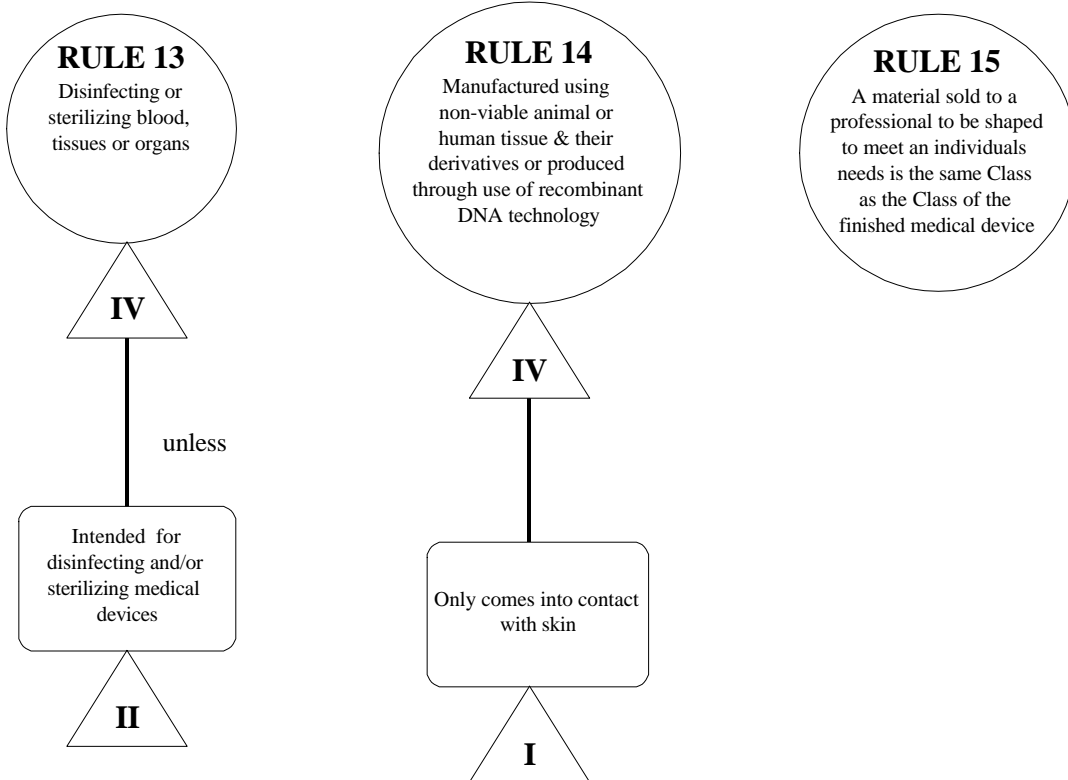
NON-INVASIVE DEVICES



ACTIVE DEVICES



SPECIAL RULES



3.3 Invasive Device Rules

Rule 1:

The rule starts by placing all SURGICALLY INVASIVE DEVICES into Class II. For example all disposable **surgical instruments** are Class II. Other examples would be:

- Short term, intravascular catheters
- X-ray detectable, nonabsorbable internal sponges

Rule 1 then introduces the corollary that if the device is intended to diagnose, monitor, control or correct a defect of the CENTRAL CARDIOVASCULAR SYSTEM, the central nervous system or of a fetus in utero, it is a Class IV device. Examples of such devices in Class IV are:

- Aneurysm Clips
- HIS bundle detectors
- Implanted spinal cord stimulators for pain relief
- Fetal blood sampling endoscope and accessories
- Transabdominal amnioscope (fetoscope and accessories)

The second corollary to Rule 1 is that a SURGICALLY INVASIVE DEVICE that is intended to be absorbed by the body, or that is normally intended to remain in the body for a least 30 consecutive days, is Class III. Examples of such devices are:

- Peritoneal, long term indwelling catheters
- Internal saline inflatable breast prosthesis
- Shoulder prosthesis
- Absorbable, synthetic, polyglycolic acid sutures
- Amalgam alloy
- Tooth shade resin material

Rule 2:

In a fashion similar to Rule 1, Rule 2 starts by placing all devices that are invasive through a BODY ORIFICE or that comes into contact with the surface of the eye, in Class II. Examples of such devices are:

- Laryngoscope
- Balloon, retention type catheter
- Daily wear, soft contact lenses

Rule 2 then introduces the corollary that if such an INVASIVE DEVICE is placed in the oral or nasal cavities as far as the pharynx or in the ear canal up to the ear drum then they are Class I.

Examples of such devices are:

- Oropharyngeal airway (anaesthesiology)
- Tympanoscope
- Intra-nasal, septal splint

The second corollary to Rule 2 states that should a device that is invasive via a BODY ORIFICE or that is in contact with the surface of the eye, remain so for 30 consecutive days or longer, it is a Class III device. Examples of devices that would fall under this corollary are:

- Intrauterine contraceptive device
- Tracheal stent

The third corollary to Rule 2 states that if the device is intended to prevent the transmission of infectious agents during sexual activity, it is a Class III device. An example of such a device would be:

- A female condom

Rule 3:

Rule 3 overrides rules 1 and 2 and is a “special” rule for **INVASIVE DEVICES**.

The first corollary places denture materials and orthodontic appliances in Class II. Without this corollary, devices of this nature would be Class I by Rule 2(2). Because devices of this nature have repeated short term contact with mucous membranes, they have been moved up to Class II.

Examples of devices which would be Class II by this rule are:

- Orthodontic brackets
- Over the Counter Denture Repair Kits
- Preformed Dentures
- Plastic Teeth

The second corollary to this rule states that all **SURGICAL OR DENTAL INSTRUMENTS** as classified as Class I. Surgical and dental instruments are understood to be reusable and not single use disposable. Without this corollary reusable instruments would be Class II by Rule 1(1).

The third corollary to Rule 3 states that all latex condoms are Class II.

3.4 Non - Invasive Device Rules

Rule 4:

Rule 4 places non-**INVASIVE DEVICES** that come into contact with injured skin in Class I where they are intended to be used only as a mechanical barrier for compression or for absorption of exudations.

Examples of devices that would be Class I by this rule are:

- Dressing
- Adhesive strip
- Surgical drape

Devices, with any other intended mechanism of action, which come into contact with injured skin are Class II. Examples of such products are:

- Chemical cold pack, snakebite kit
- Antimicrobial catheter cuff
- Hydrogel dressing, wound and burn

Rule 5:

This rule looks at “non-**INVASIVE DEVICES** intended for channelling or storing gases, liquids, tissues or body fluids for the purpose of introduction into the body by means of infusion or other means of administration.” Devices classified by this rule must be considered separately from devices covered in Rule 7, that have either no physical contact with the patient or only come into contact with intact skin. Devices covered by Rule 5, could be considered to be indirectly **invasive**. By this it is meant that they are generally attached to an **INVASIVE DEVICE**. For example an IV administration set is attached to the introductory needle.

Typically, devices addressed by this rule are used in transfusion, infusion, extracorporeal circulation and the delivery of anaesthetic gases and oxygen. In some cases, devices covered by this rule are very simple gravity-activated, delivery devices.

Examples of devices classified by Rule 5 are:

- Ventilator, tubing and support set
- Piston syringe
- Enteral feed bag
- Medicine spoon
- Ocular emergency irrigator
- Portable air compressor
- Flowmeter, (anaesthesia)

Rule 6:

Rule 6 covers mostly the more sophisticated elements of extracorporeal circulation sets, dialysis systems and autotransfusion systems, as well as devices for extracorporeal treatment of body fluids which may not be reintroduced immediately into the body.

Rule 6 states that devices, intended to modify the biological or chemical composition of blood or other body fluids or liquids for the purpose of introduction into the body by means of infusion or other means of administration, are Class III. Examples of devices that would be classified by this section of the rule are:

- Automatic delivery peritoneal dialysis system
- Hollow fibre capillary dialyser
- Parallel flow dialyser

Many devices involved in dialysis and hemoperfusion are also covered by Rule 11. However, both Rule 11 and Rule 6 place them in Class III.

The first corollary to this rule addresses those products which, during the modification process, may introduce back into the body a foreign substance in a potentially dangerous concentration. Certain stem cell separators and ex vivo photodynamic cell processors would be Class IV by this corollary.

The second corollary recognizes that products which achieve their intended modification through filtration, centrifugation or the exchange of heat or gas are more appropriately classified as Class II. Examples of devices of this nature are:

- Cardiotomy suction line blood filter
- Cardiopulmonary bypass oxygenator
- Cardiopulmonary bypass heat exchanger
- Anaesthetic conduction filter

Rule 7:

Rule 7 is a fall back rule, intended to cover all other non-INVASIVE DEVICES not addressed by a more specific rule.

Examples of devices which are Class I by Rule 7 are:

- Thoracic drainage system, water seal
- Manual, adjustable, hospital bed

The products mentioned above, in general come into contact only with intact skin or do not touch

the patient at all. These devices may however, be connected to the patient by means of a catheter or other tubing. *Non-invasive receptacles intended for biological samples for in vitro diagnostic examination are not covered by this guide.*

There are two corollaries to Rule 7. The first states that should the device act as a calibrator, tester or quality control support to another MEDICAL DEVICE it is classified as Class II. Only calibrators, testers and quality control support products offered for sale as part of MEDICAL DEVICE systems or as MEDICAL DEVICES themselves fall under this category. These calibrators or testers must be employed to test or calibrate a MEDICAL DEVICE prior to or during every use in order to ensure the proper functioning of the device. Equipment used to repair a malfunctioning product is not considered to be a calibrator or tester for the purpose of these rules. This category does not include products used in periodic servicing and maintenance. Moreover, it should be noted that calibrators and testers used during the manufacturing process are not MEDICAL DEVICES.

Examples of products that would be classified by this rule are:

- Pacemaker, generator function analyser
- Anaesthesia unit, calibrator
- Gas pressure calibrator
- Electrosurgical alarm system
- Dialysis unit test equipment
- Radiographic test pattern

The second corollary to this rule states that if a Class I MEDICAL DEVICE is intended to be connected to an **active device** that is classified as Class II, or higher, then it becomes a Class II device.

Examples of such products are:

- Gas pressure transducer
- Transcutaneous, oxygen electrode
- Heart sound transducer
- Tens cable/lead
- Ultrasonic, diagnostic transducer

3.5 Active Device Rules

Rule 8:

Rule 8 deals specifically with devices intended to emit ionizing radiation. All such devices, together with any related software, are classified as Class III unless they are used only in radiographic mode, in which case they are classified as Class II. However, Mammographic X-ray systems, although used in the radiographic mode, are still Class III.

The following are examples of devices which emit ionizing radiation and are Class III:

- Gold, titanium or platinum isotope seed
- Angiographic system X-ray
- Bone densitometer
- Fixed radiographic/fluoroscopic unit

Examples of devices that are used in the radiographic mode and are Class II:

- Digital dental imaging system - filmless
- Radiographic unit, diagnostic dental (X-ray)
- Tomographic X-ray system

Rule 9:

In general, Rule 9 places all **active therapeutic** medical devices, together with any related software, into Class II.

Examples of devices that are Class II by Rule 9(1) are:

- Air pressure tourniquet
- Phototherapy timer
- Biofeedback device
- Traction unit, powered
- Scoliosis stimulator (Orthosis)
- Air-powered, dental handpieces
- Thermal infusion fluid warmer
- Non-invasive bone growth stimulator,

Rule 9 goes on to state that should the administration or withdrawal of energy by a device be potentially hazardous, taking into account the nature of the administration or withdrawal, the intensity of the energy and the part of the body concerned, the device is classified as Class III.

Examples of devices which are Class III by Rule 9(2) are:

- Electroanesthesia apparatus
- High energy DC defibrillator
- External counter-pulsating device
- Electroconvulsive therapy device
- Neurosurgical, fragmentation and aspiration device
- Cyclodestructive ultrasound device
- Surgical neodymium, YAG laser

Cranial drill

There are devices that while Class II by this corollary of Rule 9 are Class IV by the first corollary to Rule 1. Such devices include: the ventricular assist, the angioplastic coronary laser and the intra-aortic balloon system. These are good examples of where the highest classification possible applies.

Any device which meets the criteria of the first corollary to Rule 9 and also is intended to control the treatment of a patient's condition through a CLOSED-LOOP SYSTEM is classified as Class IV. What is intended by the term "CLOSED-LOOP SYSTEM" is a device which is capable of sensing, interpreting and treating the patient without a human interface at any point in the procedure.

Examples of products that would fulfill both these corollaries are:

- External, pacemaker, pulse generator
- Automatic implantable cardioverter defibrillator
- Implantable, rate responsive pacemaker
- Implanted vagus nerve stimulator (Epilepsy)

Rule 10:

Where Rule 9 addresses ACTIVE THERAPEUTIC DEVICES, Rule 10 addresses all ACTIVE DIAGNOSTIC DEVICES, including any dedicated software. Like Rule 9, in general, all such devices are classified as Class II.

Examples of devices which are Class II by Rule 10 are:

- Phonocardiograph
- Recorder, Long Term, ECG, Portable (Holter Monitor)
- Enuresis alarm (conditioned response)
- Stimulator, (photo-evoked response)
- Infrared thermometer
- Audiometer

Likewise there is a corollary to Rule 10 which is similar to that of Rule 9. It reads "A device described in subrule (1) that is intended to be used to monitor, assess or diagnose disease, a disorder, an abnormal physical state, or pregnancy, where erroneous readings could result in immediate danger, is classified as Class III."

Examples of devices which are Class III by Rule 10 are:

- Gas analyser - nitrous-oxide, gaseous phase

Gas analyser - oxygen, gaseous phase
Monitor blood gas - transcutaneous oxygen
Monitor, pulse rate
Monitor, ventilation
Monitor, blood pressure, neonatal, ultrasonic/doppler

Again with Rule 10 there are instances that while a device is Class III by Rule 10 it is Class IV by Rule 1. Examples include intracardiac oximeters, cerebral blood flow monitors and fetal ph monitors.

Rule 11:

Rule 11 is intended primarily to cover drug delivery systems and anaesthesia equipment. In general any active device including any dedicated software, intended to administer or withdraw drugs, body fluids or other substances to or from the body is classified as Class II.

Examples of devices that are classified as Class II by Rule 11 are:

Nebulizer, direct patient interface
Biopsy instrument (suction)
Infant aspirator
Jet lavage
Hysteroscopic insufflator
Operatory suction unit

The first corollary of this rule states that should the administration or withdrawal of energy be potentially hazardous, taking into consideration the nature of the substance involved and the part of the body concerned the device is classified as Class III.

Examples of devices that are classified as Class III by Rule 11 are:

Antichoke suction device
Hemoperfusion sorbent apparatus
Negative pressure, external body ventilator
Volume ventilator (Critical Care)
Semi-automatic, peritoneal dialysate delivery system
Infusion pump

Should a device meet the criteria of the first corollary and in addition function in a **CLOSED-LOOP SYSTEM**, then that device is classified as Class IV.

Closed loop, blood glucose controller

Closed loop, blood pressure controller

Rule 12:

This is a fall back rule, similar to Rule 7 for non-INVASIVE DEVICES. This Rule is intended to catch all active medical devices not addressed by the Rules 9 through 11. Many of the active devices classified by Rule 12 either do not apply energy to the patient in a therapeutic manner or are used simply to illuminate the patient's body in the visible spectrum.

Examples of devices that are Class I by Rule 12 are:

- Intraoral dental light
- Surgical television camera without audio
- Endoscopic still camera
- Surgical microscope system
- AC-powered keratoscope
- External limb component, powered hand
- Fiberoptic illuminator for an endoscope

While devices may be Class 1 by Rule 7, other rules may move them into higher classifications. For example, a portable alarm leakage detector is Class I by Rule 12 but Class II by Rule 7. Again, it is important to check all rules.

3.6 Special Device Rules

Rule 13:

Rule 13 (a) states that any device intended to disinfect or sterilize blood, tissues or organs intended for transfusion or transplantation is classified as Class IV.

Any device intended to sterilize another MEDICAL DEVICE is classified as Class II.

Examples of devices which are classified Class II by Rule 13 are:

- Steam Sterilizer
- Dry Heat Sterilizer
- Ultraviolet Sterilizer

Rule 14:

This rule states that any MEDICAL DEVICE manufactured from or incorporating non-viable or viable, animal or human tissue or their derivatives, or a product produced through the use of recombinant DNA technology, is classified as Class IV.

Examples of devices that are Class IV by Rule 14 are:

Corneal Shield, Collagen
Tissue Heart Valve
Human Lyophilized Dura Matter
Skin Grafts

However, should such a device only come into contact with intact skin, it is classified as Class I. This corollary covers devices made from leather that only contact the intact skin. An example would be leather straps on leg braces.

Rule 15:

This rule addresses *materials* that will be sold to professionals or dispensers to be formulated into a custom shape. Examples of materials that would be classified by this rule are:

Polymeric blocks used in the formation of dentures
Silicone blocks to be used in reconstructive surgery
Amalgams to be used in dentistry
Glass used in the formation of lenses
Polymeric blocks used to produce embolic devices

Rule 16:

The use of the table to Rule 16 will be covered in a future version of this guidance document.