

Study Group 1

Principles of Medical Device Classification

SG1/N015R22

Ed Woo
Medtronic Inc.
USA



General Principles

- Regulatory control proportional to risk, taking into account of the benefits of the device
- Classify based on risk
 - Patients
 - Users
 - Others
- Harmonized classification system benefits Regulatory Authorities & manufacturers



Recommendations

- Global Classification System
- Four risk classes
- Class determination based on set of rules
- Clear rules for manufacturers to self identify
- Accommodate technological developments
- Manufacturers should document justification for product classification decision
- Deviation should be weighted against disadvantages of disharmonized international classification



Influencing Factors for Classification

- Multiple rules applies – assigned to highest class
- Multiple medical devices intended to used together
 - Classification rules apply separately to each
- Assemblage of medical devices
 - Intended use different from individual MDs – classified according to new intended use
 - Same intended use – no need to classify as a whole
 - Individual MDs not yet comply w/ regulatory requirements – combination classified as whole according to intended use
- Accessories used together with “parent” MD to achieve intended purpose – same as MD
- Standalone Software
 - Drives or influences the use of separate Medical Device – classified same as device
 - Independent of other Medical Devices – classified separately



GHTF Medical Device Classification System

CLASS	RISK LEVEL	DEVICE EXAMPLES
A	Low Risk	Surgical retractors / tongue depressors
B	Low-moderate Risk	Hypodermic Needles / suction equipment
C	Moderate-high Risk	Lung ventilator / orthopedic implants
D	High Risk	Heart Valve / Implantable defibrillator

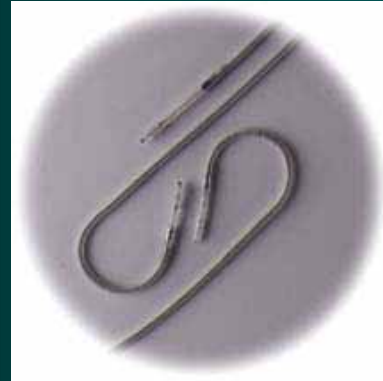


Classification Rules

- SG1/N015R22
 - Sec. 8.0 Initial Classification Rules
 - Sec. 8.1 Rational for Additional Rules
 - Appendix A Decision Trees



Case 1 Steroid Eluting Pacing Lead



- **Indications**

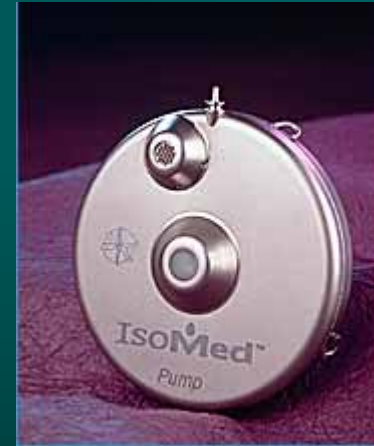
Leads are designed for use with a compatible IPG or an ICD as part of a cardiac system. Leads are intended for delivering therapies and/or sensing in the atrium and/or ventricle of the heart.

- **Steroid-elution technology** reduces inflammation. By eluting a steroid at the lead tip, leads are designed to reduce the typical tissue inflammation.

Case 2 Implantable Constant Flow Infusion System

Indications

- Chronic intrathecal infusion of preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain
- Chronic intravascular infusion of floxuridine (FUDR) for the treatment of primary or metastatic cancer



Case 3 Aortic and Mitral Bioprosthesis

Indications

- Replacement of impaired native or prosthetic aortic and mitral heart valves.

