

AUG 15 1986

MEDTRONIC CONFIDENTIAL

K961936

2) 510(k) Summary

a) Submitter

Medtronic, Inc.
7000 Central Avenue N.E.
Minneapolis, MN 55432

Contact: Nora K. Hadding, Product Regulation Associate
Telephone: (612) 574-4189
Fax: (612) 574-6424

b) Name of Device

Trade Name: Model 2188 Coronary Sinus Lead

Common Name: Pacing Lead

Classification Name: Cardiovascular permanent or temporary pacemaker electrode (21 CFR 870.3680)

c) Predicate Device

The Model 2188 lead is substantially equivalent to the Model 6992A coronary sinus lead and its predecessors. The Model 6992A coronary sinus lead has been in commercial distribution since at least 1974. Since the Model 6992A was in existence prior to medical device regulations, no FDA document control number can be referenced. In addition, the Model 2188 relies on technology used with Medtronic Models 4524, 4582, 6990, and 6991A (Document Control Numbers P830061/S12, K896313, K780621 and K772104, respectively).

d) Device Description

The Model 2188 coronary sinus lead is a bipolar coaxial polyurethane lead with an IS-1 connector and a porous tip electrode which is canted toward the lead body. The distal portion of the lead is pre-shaped at a 45° angle. The conductor coils utilize a platinum sputtered MP35N nickel-alloy material.

e) Intended Use

The Model 2188 coronary sinus lead is designed for atrial pacing and sensing in the coronary sinus. The lead has application where permanent atrial or dual-chamber pacing systems are indicated.

f) Technological Characteristics

1. Lead Characteristics

The Medtronic Model 2188 coronary sinus lead is a bipolar coaxial polyurethane pacing lead with a canted porous electrode tip (5.8 mm²) and an IS-1 connector. The distal portion of the lead is pre-shaped at a 45° angle. The Model 2188 coronary sinus lead is designed for atrial pacing and sensing applications in the coronary sinus. The lead has application where implantable atrial or coronary sinus single- or dual-chamber pacing systems are indicated.

The lead has a porous tip electrode made of platinum alloy that can be positioned in the coronary sinus. In addition, the tip is canted toward the lead body at the end to facilitate contact with the coronary sinus wall.

The lead also has a ring electrode proximal to the tip electrode and an IS-1 bipolar (BI) connector. It features platinum sputtered MP35N nickel-alloy conductor coils and polyurethane 55D insulation. The lead will be packaged in a new packaging configuration but with the same accessories as the Model 6992A pacing lead.

The following section describes in detail the physical characteristics of the Model 2188 in comparison with existing Medtronic leads.

a) Medtronic Model 4582 Target Tip Pacing Lead (Document Control Number K896313)

The Model 2188 utilizes a bipolar coaxial design with an IS-1 connector. The conductor coil is platinum sputtered MP35N nickel alloy. The Medtronic Model 4582 pacing lead features a similar coaxial design with an IS-1 connector and MP35N nickel alloy conductor coils.

b) Medtronic Model 4524 CapSure SP Pacing Lead (Document Control Number P890061/S12)

The Model 2188 pacing lead utilizes 55D polyurethane insulation. The canted electrode is platinum material and has a porous surface electroplated with platinum black. The Model 4524 CapSure SP lead utilizes the same 55D polyurethane insulation and tip electrode technology. However, the Model 2188 does not contain steroid in the tip electrode and it is canted toward the lead body. The Model 2188 and Model 4524 also share an identical IS-1 connector.

c) Medtronic Models 6990 and 6991A Pacing Leads (Document Control Numbers K780621 and K772104)

The Model 2188 coronary sinus lead utilizes an electrode tip which is canted toward the lead body to better facilitate contact with the coronary sinus vein. Models 6990 and 6991A also utilized a canted tip electrode

2. Package Characteristics

The Model 2188 coronary sinus lead will be provided in a package which uses an uncoated and silicone-coated polyethylene terephthalate, glycol modified (PETG) material. This package was successfully qualified for use with the Model 2188 lead.

g) Summary of Studies

The following studies were performed to ensure that the Model 2188 lead meets all of its design and performance requirements. In addition, the suitability of the new leads package was evaluated.

1. In Vitro/Bench Testing

To evaluate the Model 2188 coronary sinus lead, the following in vitro testing was performed:

- A. Environmental Conditioning
- B. Mechanical Testing
- C. Electrical Testing

The Model 2188 pacing lead passed all of the in vitro bench test requirements.

2. In Vivo Canine Testing

The data generated as a result of this testing demonstrated that the pacing and sensing thresholds produced by the Model 2188 coronary sinus lead is substantially equivalent to the Model 6992A coronary sinus lead.

3. Package Qualification Testing

A new package was designed for this lead. Package qualification testing was performed as follows:

- A. Ethylene Oxide (EtO) Sterilization Conditioning/Testing (Environmental Conditioning)
- B. Visual Inspection Testing
- C. Packaging Conditioning/Testing
- D. Lead Mechanical Testing
- E. Lead Electrical Testing
- F. Shelf Life Testing

The testing demonstrated the suitability of this new package for containing and protecting Medtronic leads.

4. Biocompatibility Testing

a) Lead Biocompatibility

Biocompatibility information for the materials used in the Model 2188 coronary sinus lead is presented. The materials were approved for use with Medtronic CapSure SP Model 4524 (Document Control Number P830061/S12).

b) Package Biocompatibility

The use of uncoated PETG was approved for use with Medtronic pulse generators in PMA Supplements P850051/S44, P850051/S49 and P890003/S30.

Biocompatibility information for the silicone-coated PETG used with the new package was performed and proved to be biocompatible.

c) Sterilization Validation

All Medtronic leads are sterilized using a 100% Ethylene Oxide (EtO) sterilization process. A process appropriate for sterilizing the Model 2188 coronary sinus lead was validated.

5. Conclusion

The testing described above provides reasonable assurance that the Medtronic Model 2188 coronary sinus lead will perform as intended when used in accordance with its labeling. Additionally, based on similarities in design, materials, in vitro test data and canine in vivo electrical performance, Medtronic considers the Model 2188 coronary sinus lead to be substantially equivalent to the Model 6992A coronary sinus lead and other Medtronic pacing leads found to be substantially equivalent to preregulation leads.

In addition, the new package met all qualification requirements. As such, the testing demonstrated the suitability of this new package for containing and protecting Medtronic leads.