

SECTION 6. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Device Name

StableMapr Steerable Intracardiac Electrode Catheters

Device Description

The StableMapr Series of EP Diagnostic Catheters are used to record electrical activity from within the heart and its vasculature and to stimulate the heart in accordance with various programmed electrical stimulation protocols incorporated into an EP diagnostic study. All catheters connect physician stimulator/recorder equipment to the desired region of the heart and carry analog signals. Data from the EP study is used to assess arrhythmia patient prognosis, guide therapy selection and evaluate the effectiveness of previously selected therapeutic interventions.

The StableMapr Catheters are closed-lumen diagnostic electrophysiology catheters with a variable number of platinum alloy recording/stimulating electrodes fixed around the catheter shaft. The most distal electrode is located at the catheter tip. The StableMapr Catheters include addition mapping electrodes and a preformed distal tip section, as well as other minor modifications for improved manufacturability. The electrode bands are welded to electrical wires incorporated inside the shaft of the catheter that run from each electrode to the electrical connector at the proximal end of the catheter. The outside diameter of the catheter is 7 French and the usable length ranges from 60 to 125 cm. A manipulator handle at the proximal end of the catheter permits the physician to vary the angle of curvature of the catheter tip. All models have controls in the handle to vary the radius of curvature, and the distal end of some models may be laterally deflected.

Intended Use

The Medtronic CardioRhythm StableMapr Catheter is intended for use in diagnostic electrophysiologic procedures. These catheters are designed for recording intracardiac electrograms and temporary pacing associated with electrophysiology studies.

Substantial Equivalence

The StableMapr series of EP catheters is substantially equivalent to the Medtronic CardioRhythm Marinr EP catheter, as well as the Irvine Biomedical Steerable Atrial Mapping Inquire H and Cordis Webster Halo XP Tricuspid Mapping Catheters.

Catheter Testing Results and Conclusion

The StableMapr catheter is constructed of similar materials to those found in the Medtronic CardioRhythm Marivr Catheter. The patient contacting materials utilized in the fabrication of the StableMapr are identical to those used in the Marivr catheter. Therefore, all biocompatibility testing was fulfilled via the predicate Marivr Catheter device.

The non-clinical testing were conducted in accordance with applicable FDA guidance. The tests quantified and confirmed the adequacy of electrical and mechanical performance and reliability of the Marivr catheters. These tests support the substantial equivalence of the StableMapr catheters with the predicate device.



AUG - 5 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kristen Honl
Senior Product Regulation Manager
Medtronic CardioRhythm
1312 Crossman Avenue
Sunnyvale, CA 94089-1113

Re: K981642
StableMapr Steerable Intracardiac Electrode Catheter
Regulatory Class: II (two)
Product Code: DRF
Dated: May 6, 1998
Received: May 8, 1998

Dear Ms. Honl:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981642

Device Name: StableMapr Steerable Intracardiac Electrode Catheters

Indications For Use: The Medtronic CardioRhythm StableMapr catheter is intended for use in diagnostic electrophysiology procedures. These catheters are designed for recording intracardiac electrograms and temporary pacing associated with electrophysiology studies.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Signature)

Invasive, Respiratory,
Medical Devices
510(k) Number K981642

Prescription Use

OR
(Per 21 CFR 801.109)

Over-The-Counter Use

(Optional Format 1-2-96)