K022380
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OCT 01 2002

510(k) Summary

(as required by 21 CFR 807.92)

A. Submitter Information

Submitter's Name:	St. Jude Medical, DAIG Division
Address:	14900 Minnetonka Industrial Blvd Minnetonka, Minnesota 55345-2126 U.S.A.
Telephone Number:	(952) 933-4700
Contact Person:	Jim M. Taufen
Date Submission Prepared:	19-July-2002

B. Device Information

Common or usual Name:	Diagnostic Electrophysiology Catheter
Classification Name:	Catheter, Electrode Recording
Predicate Device:	Electrophysiology Catheter DAIG Corporation
Device Description/Intended Use:	The electrophysiology catheters are manufactured in various fixed and deflectable curve profiles and electrode spacings for electrophysiological mapping for the evaluation of a variety of cardiac arrhythmias from endocardial and intravacular sites.
Indications for Use:	SJM-Daig Electrophysiology Catheters can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

C. Comparison of Required Technological Characteristics

All technological characteristics of the SJM-Daig Livewire Electrophysiology Catheters are substantially equivalent to the predicate SJM-Daig Electrophysiology Catheter including product design, materials, packaging, and sterilization.

D. Performance Data

Related published literature was cited in K002976 to show Safety and Effectiveness of the use of electrophysiology diagnostic catheters to evaluate cardiac arrhythmias from endocardial and intravascular sites.

E. Conclusion

In accordance with the FDA guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device,' issued January 10, 1997; the new labeling is being submitted to FDA as part of a new 510(k) Change Being Effected. SJM-Daig intends to continue to market the Livewire device with the amended labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 01 2002

St. Jude Medical
c/o Mr. Jim M. Taufen
Sr. Regulatory Affairs Specialist
Daig Division
14901 DeVeau Place
Minnetonka, MN 55345

Re: K022380
Trade Name: Livewire™ Electrophysiology Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter
Regulatory Class: Class II (two)
Product Code: DRF
Dated: July 19, 2002
Received: July 22, 2002

Dear Mr. Taufen:

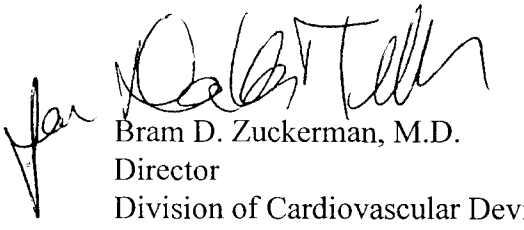
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022380

510(k) Number (if known): K022380

Device Name: St. Jude Medical, Daig Division™ Electrophysiology Catheter (Livewire™)

Indications for Use:

SJM-Daig electrophysiology catheters can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022380

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)