K012523

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Submitter: SterilMed, Inc.

Contact Person: Patrick Fleischhacker
11400 73rd Avenue North
Minneapolis MN, 55369
Ph: 888-856-4870
Fax: 763-488-3350

Date Prepared: August 3, 2001

Trade Name: SterilMed Reprocessed Electrophysiology Diagnostic Catheters

Classification Name: and Number: Class II, 21 CFR 870.1220

Product Code: DRF

Predicate Device(s): The SterilMed reprocessed electrophysiology diagnostic catheter is substantially equivalent to: the A20 (K953768), manufactured by Biosense Webster (formerly known as Cordis Webster), the Bard Dynamic Tip Catheter (K912213), and the Bard Intracardiac Electrode Catheter manufactured by C.R. Bard Inc., the Stablemapr EP Diagnostic Catheter (K981642), manufactured by Medtronic Inc., and the original manufacturers' devices.

Device Description: The device consists of a reprocessed catheter that has a high-torque shaft with a handle at the proximal end, and may or may not be steerable. These catheters have an outer diameter of 4F to 8F, a length ranging from 60 to 160 cm, with 2-20 platinum, radiopaque electrodes along the tip shaft and a variety of inter-electrode spacings and curve styles at the tip. The tip generally is deflectable. Specific cables, as recommended by the original manufacturer, connect to the handle and interface between the catheter and an external stimulator and/or an electrophysiologic recorder. It should be noted that this submission pertains to the catheter only. It does not include any other components in a system such as, connector cables, external stimulators, or electrophysiologic recorders.

Intended Use:	These cardiac diagnostic catheters are intended for temporary use during electrophysiology studies for intracardiac sensing, recording, and stimulation. They also provide temporary pacing for the evaluation of cardiac arrhythmias, and are used for electrophysiology mapping of cardiac structures during these evaluations.
Functional and Safety Testing:	Representative samples of reprocessed electrophysiology diagnostic catheters underwent design testing to demonstrate appropriate functional characteristics. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging. In addition, the manufacturing process includes visual and functional testing of all products produced.
Conclusion:	The electrophysiology diagnostic catheters reprocessed by SterilMed are substantially equivalent to the A20 (K953768), manufactured by Biosense Webster (formerly known as Cordis Webster), the Bard Dynamic Tip Catheter (K912213), and the Bard Intracardiac Electrode Catheter manufactured by C.R. Bard Inc., the Stablemapr EP Diagnostic Catheter (K981642), manufactured by Medtronic Inc., and the reprocessed devices' counterparts from the original manufacturers. This conclusion is based upon the fact that these devices' are essentially identical to the predicate devices in terms of functional design, materials, indications for use, and construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 4 2002

SterilMed, Inc.
c/o Mr. Patrick Fleischhacker
Vice President of Regulatory and Quality
11400 73rd Avenue North
Minneapolis, MN 55369

Re: K012523
Trade Name: Reprocessed Electrophysiology Diagnostic Catheters
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter
Regulatory Class: Class II (two)
Product Code: DRF
Dated: May 20, 2002
Received: May 21, 2002

Dear Mr. Fleischhacker:

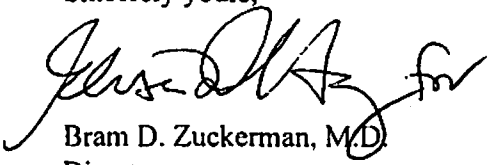
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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

Indications for Use Page

Device Name: Reprocessed Electrophysiology Diagnostic Catheters

Indications for Use:

The Reprocessed Electrophysiology Diagnostic Catheters are intended for temporary use during electrophysiology studies for intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias; and for electrophysiologic mapping of cardiac structures during these evaluations.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices
510(k) Number K012523

8/14/02

Prescription Use X
(Per 21 CFR 801.109)