DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2004

SterilMed, Inc.
c/o Dr. Bruce Lester
Vice President Research and Development
11400 73rd Avenue North
Minneapolis, MN 55369

Re: K012678 – Supplemental Validation Submission
Trade Name: See Enclosed List
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter
Regulatory Class: Class II (two)
Product Code: NLH
Dated: August 13, 2001
Received: August 14, 2001

Dear Dr. Lester:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on August 14, 2002 . We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter are 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 these devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (PMA) they 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 devices 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 devices comply 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 applicable 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.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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

Enclosures

Enclosure – List of Devices

Orig models found to be SE
Daig (132)
401206
401207
401209
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401222
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Orig models found to be SE
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Orig models found to be SE
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401859
401860
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Orig models found to be SE
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Indications for Use Page

Device Name: Reprocessed Sealed Electrophysiology Diagnostic Catheters

Indications for Use:

The Reprocessed Sealed 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 K012628

Prescription Use X
(Per 21 CFR 801.109)

AUG 1 4 2002

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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 13, 2001

Trade Name: SterilMed Reprocessed Sealed Electrophysiology Diagnostic Catheters

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

Product Code: DRF

Predicate Device(s): The SterilMed reprocessed sealed 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 manufacturer's 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 7F, a length ranging from 65 to 120 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.

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Intended Use:	The reprocessed sealed 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.
Functional and Safety Testing:	Representative samples of reprocessed sealed 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 sealed and 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 manufacturer. 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.