JAN 1 8 2002

SECTION 2. SUMMARY AND CERTIFICATION

K012684

A. 510(k) Summary

Submitter: SterilMed, Inc.

Contact Person: Patrick Fleischhacker
11400 73rd Avenue North
Minneapolis, MN 55369
Ph: 888-856-4870
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Date Prepared: August 11, 2001

Trade Name: SterilMed Reprocessed Electrosurgical Electrodes

Classification Name and Number: Electrosurgical Device, Class II, 21 CFR 878.4400

Product Code: JOS

Predicate Device(s): SterilMed's Reprocessed electrosurgical electrodes are substantially equivalent to:

- The Colorado Micro-Dissection Needle manufactured by Stryker Leibinger / Colorado Biomedical Inc (K000348)
- Similar devices from other manufacturers

Device Description: SterilMed's reprocessed electrosurgical electrodes are a monopolar electrosurgical instruments consisting of a tungsten tip, stainless steel housing, and several layers of insulation.

Intended Use: Reprocessed electrosurgical electrodes are intended for precision cutting or dissecting and cauterizing soft tissue. These devices are most commonly used in surgical procedures for which minimal tissue necrosis, bleeding, and surgical field smoke is desired.

Functional and Safety Testing: Representative samples of reprocessed electrosurgical electrodes underwent bench 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 electrosurgical electrodes reprocessed by SterilMed are substantially equivalent to:

- The Colorado Micro-Dissection Needle manufactured by Stryker Leibinger / Colorado Biomedical Inc. (K000348)
- Similar devices from other manufacturers

This conclusion is based upon the fact that the subject device is identical to their predicate device in terms of functional design, materials, indications for use, and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 8 2002

Mr. Patrick Fleischhacker
Vice President, Regulatory
and Quality Control
SterilMed, Inc.
11400 73rd Avenue North
Maple Grove, Minnesota 55369

Re: K012684
Trade/Device Name: Reprocessed Electrosurgical Electrodes
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 6, 2001
Received: December 7, 2001

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) 594-4659. 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,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use Page

K012684

Device Name: Reprocessed electrosurgical electrodes, or reprocessed electrosurgical electrodes.

Indications for Use:

Reprocessed electrosurgical electrodes are intended for precision cutting, dissecting and cauterizing of soft tissue. These devices are most commonly used in surgical procedures for which minimal tissue necrosis, bleeding, and surgical field smoke is desired.

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012684