JAN 13 2005

510(k) Summary Statement K043135

Date Prepared: November 8, 2004

Submitter's Name/Address: SPSmedical Supply Corp.
6789 West Henrietta Road
Rush, NY 14543

Contact Person: Gary J. Socola, Vice President
Phone (585)-624-2419

Trade Name: SporView® PA Culture Set

Classification: Sterilization Process Indicator - 21 CFR 880.2800 (a) Class II

Predicate Device: Castle® SPOR-TEST PA Biological Indicator Kit (K020205)

Device Description:

SporView® PA Culture Set is intended to monitor the STERIS System 1® peracetic acid sterilization process using the STERIS® 20 sterilant. The product contains paper strips that are inoculated with *G. stearothermophilus* spores (formally known as *Bacillus stearothermophilus*) at a nominal population of 1×10^5 per strip. Sterile tubes of SporView® Culture Media (modified soybean casein broth) and a transfer clip are included. The product is intended to be used in an identical manner as the Castle® SPOR-TEST PA Biological Indicator Kit.

Intended Use:

The SporView® PA Culture Set is only intended to monitor the STERIS System 1® liquid chemical sterilization system using STERIS® 20 sterilant. The SporView® PA Culture Set was qualified using SporView® Culture Media. The use of the product is restricted to the SporView® biological indicator spore strip and media only. When tested at 1,000 ppm peracetic acid, 50°C, the SporView® PA Culture Set will survive at 41 seconds and will be killed at 6 minutes.

Comparison to the Predicate Device:

- Both devices are exclusively used to monitor the STERIS System 1® peracetic acid process.
- Both devices are assessed in process conditions of 1000 parts per million peracetic acid at 50°C.
- Both devices use a paper carrier inoculated with 10^5 spores of *G. stearothermophilus*
- Both devices are processed in the sterilizer when held by a transfer clip.
- Both devices are open-loop biological indicators that are recovered in tubes of sterile growth media.
- Both use a growth medium that is modified with a color change indicator.
- Both devices may only monitor sterilization efficacy on exterior surfaces loads processed in the STERIS System 1® peracetic acid process.

Conclusion:
The SporView® PA Culture Set is substantially equivalent the Castle® SPOR-TEST PA Biological Indicator Kit for monitoring the STERIS System 1® peracetic acid process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2005

Mr. Gary J. Socola
Vice President, Scientific Affairs
SPSmedical Supply Corporation
6789 West Henrietta Road
Rush, New York 14543

Re: K043135
Trade/Device Name: SporView® Peracetic Acid Culture Set
Regulation Number: 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: MRB
Dated: December 29, 2004
Received: January 3, 2005

Dear Mr. Scola:

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), please contact the Office of Compliance at (301) 594-0115. 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS for USE STATEMENT

Applicant: SPSmedical Supply Corp.

510(k) Number (if known): K043135

Device Name: SporView® Peracetic Acid Culture Set

Indications For Use:

The SPSmedical SporView® PA Culture Set is intended for use with the STERIS System 1® sterilizer using STERIS® 20 sterilant only. The STERIS System 1® is a liquid chemical sterilization process. The SporView® PA Culture Set provides independent confirmation that sterilization conditions were achieved during the STERIS System 1® processing cycle. A reduced incubation time of 24 hours has been validated for the SporView® PA Culture Set using SPSmedical's SporView® culture media.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lynette M. Michaels MD.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K043135