K081879

510(k) Summary of Safety and Effectiveness

JUL 30 2008

Submitter:

- SPSmedical Supply Corp.
  6789 West Henrietta Road
  Rush, NY 14543 U.S.A.
  Phone: (585)-359-0130 Fax: (585)-359-0167
- Establishment FDA Registration No.: 1319130
- Date Summary was Prepared July 29th, 2008
- Gary J. Socola
  Printed name of person submitting for 510(k)

Gary J. Socola

- _____
  Signature of person submitting for 510(k)
- Vice President, Scientific Affairs
  Title of person submitting for 510(k)

Device Name and Classification

Trade Name:	SPSmedical SporView® PA Culture Set
Classification Name:	Sterilization Process Biological Indicator
Common Name:	Peracetic Acid Culture Set
Device Classification:	Class II, Regulation Number 880.2800
Product Code:	80MRB
Predicate Device:	SPSmedical SporView® PA Culture Set (K043135)

Device Description:

SporView® PA Culture Set is intended to monitor the STERIS System 1® sterilization process, with STERIS® 20 sterilant. The product contains paper strips that are inoculated with *G. stearothermophilus* spores. Sterile tubes of SporView® Culture Media (modified soybean casein broth) and a transfer clip are included.

Intended Use:

The SporView® PA Culture Set is only intended to monitor the STERIS System 1® liquid chemical sterilization system, with 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 and media only. SPSmedical's PA Culture Set has been validated for a reduced incubation time of 16 hours.

Statement of Similarity to the Legally Marketed Predicate Device:

- ☐ Have the same indicated use
- ☐ Incorporate the same materials
- ☐ Packaged using the same materials and processes

Non-Clinical Testing:

Testing was conducted following the FDA guidance for the validation of reduced incubation of biological indicators. Testing was performed for the peracetic acid sterilization process using three lots of biological indicators. All lots were tested using SPSmedical's SporView® Culture Media. All lots tested resulted in a 16 hour reduced incubation time for the peracetic acid sterilization process when using the SPSmedical SporView® PA Culture Set.

Conclusion:

Supportive data has demonstrated that the SPSmedical SporView® PA Culture Set is equivalent to the legally marketed predicate device. Results of performance testing validate that the SPSmedical SporView® PA Culture Set provides a 16 hour reduced incubation time when monitoring the peracetic acid sterilization process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUL 30 2008

Re: K081879
Trade/Device Name: SPSmedical SporView® Culture Set
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: MRB
Dated: July 1, 2008
Received: July 2, 2008

Dear Mr. Socola:

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.

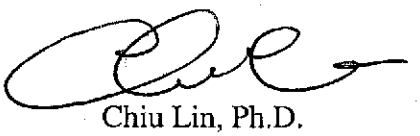
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Applicant: SPSmedical Supply Corp.

510(k) Number (if known): K081879

Device Name: SPSmedical SporView® PA 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 SporView® PA Culture Set provides independent confirmation that sterilization conditions were achieved during the STERIS System 1® processing cycle. A reduced incubation time of 16 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)

Shirley A Murphy MD

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

510(k) Number: K081879