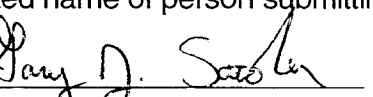
K023716

510(k) Summary of Safety and Effectiveness

Submitter:

DEC 0 5 2002

- 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 November 1st, 2002
- Gary J. Socola
  Printed name of person submitting for 510(k)
- 
  Signature of person submitting for 510(k)
- Director of Quality Assurance
  Title of person submitting for 510(k)

Device Name and Classification

Trade Name:	SPSmedical SporView® Bacterial Spore Strip
Classification Name:	Sterilization Process Biological Indicator
Common Name:	Spore Strip Biological Indicator
Device Classification:	Class II, Regulation Number 880.2800
Product Code:	FRC
Predicate Device:	SPSmedical SporView® Bacterial Spore Strip (K905425)

Device Description:

The SPSmedical SporView® Bacterial Spore Strip is a .250" x 1 1/2" Whatman 3MM chromatography filter paper inoculated with either a single species (*Geobacillus stearothermophilus* ATCC# 7953) or a dual species (*Geobacillus stearothermophilus* ATCC# 7953 and *Bacillus atrophaeus* ATTC# 9372) bacterial spores. The strip is packaged in a blue glassine envelope.

Intended Use:

The SPSmedical SporView® Bacterial Spore Strip is designed for routine monitoring of Steam, Dry Heat, EO Gas, and Chemiclave® sterilization processes. For steam sterilizers operating at 121°C and at 132°C a 24 hour incubation time has been validated. The indicator should be placed in the most difficult to sterilize location of the sterilization load. After cycle completion, the spore strip is removed from the load and aseptically transferred into SPSmedical's SporView® Culture Media (Tryptic Soy Broth with Bromocresol Purple) and incubated at 60°C. The combination of SPSmedical's spore strip and media has been validated for a reduced incubation time of 24 hours for steam processes. For Dry Heat, EO Gas, or Chemiclave® sterilization processes, the incubation period is seven (7) days

Statement of Similarity to the Legally Marketed Predicate Device:

- Have the same indicated use
- Incorporate the same materials
- Have the same shelf life
- 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 steam sterilization process using three lots of biological indicators; this included a newly manufactured lot, mid-range expiration lot and a lot nearing its expiration date. All lots were tested using SPSmedical's SporView® Culture Media (Tryptic Soy Broth, Modified with Bromocresol Purple). All lots tested resulted in a 24 hour reduced incubation time for the steam sterilization process when using the combination of the SPSmedical SporView® Bacterial Spore Strip and the SPSmedical's SporView® Culture Media.

Conclusion:

Supportive data has demonstrated that the SPSmedical SporView® Bacterial Spore Strip is equivalent to the legally marketed predicate device. Results of performance testing validate that the SPSmedical SporView® Bacterial Spore Strip provides a 24 hour reduced incubation time when used with the SPSmedical SporView® Culture Media in monitoring the steam sterilization process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 5 2002

Mr. Gary J. Socola
Director, Quality Assurance
SPSmedical Supply Corporation
6789 West Henrietta Road
Rush, New York 14543

Re: K023716
Trade/Device Name: SPSmedical SporView® Bacterial Strip
Regulation Number: 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: November 1, 2002
Received: November 5, 2002

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 Office of Compliance at (301) 594-4618 . 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,

Timothy A. Ulatowski
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): K023716

Device Name: SPSmedical SporView® Bacterial Spore Strip

Indications For Use:

The SPSmedical SporView® Bacterial Spore Strip is designed to monitor steam sterilizer cycles at 121°C and 132°C. The combination of SPSmedical's spore strip and SporView® Culture Media (Tryptic Soy Broth, Modified with Bromocresol Purple) has been validated at 60°C for a reduced incubation time of 24 hours for steam sterilization processes.

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

510(k) Number: K023716

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)