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510(k) Summary of Safety and Effectiveness

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 May 5th, 2005
- 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®*Plus* BI Test Pack
Classification Name:	Biological Indicator
Common Name:	Biological Test Pack
Device Classification:	Class II, Regulation No. 880.2800
Product Code:	80FRC
Predicate Device:	SPSmedical SporView® BI Test Pack (K022706)

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Device Description:

The SPSmedical modified SporView®*Plus* Steam BI Test pack is a single use PCD used for the monitoring of both gravity displacement and pre-vacuum steam sterilization cycles.

Intended Use:

The SPSmedical SporView®*Plus* Steam BI Test pack is designed to monitor sterilization cycles in both gravity displacement and pre-vacuum steam sterilizers. It is to be used for routine and challenge monitoring of steam sterilizers.

Statement of Similarity to the Legally Marketed Predicate Device:

- Have the same indicated use
- Are run in the same sterilization cycles
- Incorporate the same materials
- Have the same shelf life
- Have the same storage conditions
- Packaged using the same materials and processes

Non-Clinical Testing:

Testing was performed in a 121°C (250°F) gravity displacement sterilizer and in a pre-vacuum steam sterilizer operating at 132°C (270°F). Three separate lots of biological indicators containing *G. stearothermophilus* spores were used. The validation study involved preparing AAMI biological indicator test packs as indicated in AAMI standard ST-46:2002, section 7.5.2. A biological indicator and STEAM*Plus* Integrator were placed within the center of each AAMI biological indicator test pack and within the SporView®*Plus* Steam BI Test pack. Complete survival, partial survival and complete kill cycles were run in a gravity displacement steam sterilizer at 121°C (250°F) and in a prevacuum steam sterilizer operating at 132°C (270°F). The biological indicators in the SporView®*Plus* BI Test packs were found to be equivalent in performance to those located within the AAMI biological indicator test packs. In addition a biological indicator and STEAM*Plus* Integrator were placed within the center of the predicate test pack and within the SporView®*Plus* Steam BI Test pack. Complete survival, partial survival and complete kill cycles were run in a gravity displacement steam sterilizer at 121°C (250°F) and in a pre-vacuum steam sterilizer operating at 132°C (270°F). The biological indicators in the SporView®*Plus* BI Test packs were found to be equivalent in performance to those located within the predicate test packs.

Conclusion:

SPSmedical SporView®*Plus* Steam BI Test pack has undergone appropriate validation. For all the foregoing reasons, SPSmedical believes that the SporView®*Plus* Steam BI Test pack is equivalent to the predicate SPSmedical pack when used for routine and challenge monitoring of steam sterilizers and can be safely marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2005

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

Re: K051173
Trade/Device Name: SporView®Plus Steam BI Test Pack
Regulation Number: 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: May 5, 2005
Received: May 9, 2005

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 (240) 276-0115. 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/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 STATEMENT

Applicant: SPSmedical Supply Corp.

510(k) Number (if known): K051173

Device Name: SporView®*Plus* Steam BI Test Pack

Indications For Use:

The SPSmedical SporView®*Plus* Steam BI Test Pack with STEAM*Plus* Integrator is indicated for use in routine and challenge testing of steam gravity displacement cycles at 121°C/250°F for 30 minutes exposure time or longer and for use in pre-vacuum steam sterilization cycles at 132°C/270°F for 4 minutes exposure time or longer.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X (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)

Division Sign-Off)
Office of Anesthesiology, General Hospital,
Infection Control, Dental Devices
(510(k) Number: K051173