JUL 18 2002 K020409

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 July 12, 2002
- Gary J. Socola
  Printed name of person submitting for 510(k)
- Gary J. Socola
  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 STEAM*Plus*™ Sterilizer Test Pack
Classification Name:	Sterilization Process Indicator
Common Name:	Steam Challenge Test
Device Classification:	Class II, Regulation Number 880.2800
Product Code:	80JOJ
Predicate Device:	Propper Pass/Fail Steam Challenge Pack (K991276)

Device Description:

The SPSmedical STEAM*Plus*™ Sterilizer Test Pack consists of a steam sterilization integrator placed inside a package of porous and non-porous material. The SPSmedical STEAM*Plus*™ Sterilizer Test Pack is designed to create a significant challenge to air removal and steam penetration.

Intended Use:

The SPSmedical STEAM*Plus*™ Sterilizer Test Pack is designed to monitor sterilization cycles in gravity displacement steam sterilizers at 121°C and in prevacuum steam sterilizers at 132°C. It is to be used for routine monitoring and challenge testing of steam sterilizers and can be used in conjunction with a biological indicator test pack.

Technical Characteristics:

The SPSmedical STEAM*Plus*™ Sterilizer Test Pack has the same intended use and technological characteristics as the AAMI biological indicator test pack and other commercially available test packs. The SPSmedical STEAM*Plus*™ Sterilizer Test Pack is designed to create a significant challenge to air removal and steam penetration. The SPSmedical STEAM*Plus*™ Sterilizer Test Pack adds resistance and impedes steam penetration to the steam sterilization integrator located within the pack. This provides a significant challenge to the steam sterilization process.

Non-Clinical Testing:

Two hundred ten (210) sterilization tests were run to compare performance standards/results of the SPSmedical STEAM*Plus*™ Sterilizer Test Pack to the AAMI biological indicator test pack. A biological indicator strip containing *Bacillus stearothermophilus* spores was used within the AAMI biological indicator test pack along with a STEAM*Plus*™ integrator. Of the two hundred and ten sterilization tests that were run; 60 comparison tests for failures were orchestrated, 90 comparison tests for pass/failures were orchestrated and 60 tests for passing results were orchestrated. The pass and failure sterilization testing of SPSmedical STEAM*Plus*™ Sterilizer Test Pack consistently showed results comparable to the AAMI biological indicator test pack.

Conclusion:

Supportive data has demonstrated that the SPSmedical STEAM*Plus*™ Sterilizer Test Pack is equivalent to the predicate device. Results of performance testing indicate that the SPSmedical STEAM*Plus*™ Sterilizer Test Pack provides a sufficient load challenge to monitor steam gravity displacement sterilization cycles at 121°C and for prevacuum steam sterilization cycles at 132°C. The SPSmedical STEAM*Plus*™ Sterilizer Test Pack is an effective and reliable, single use device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2002

Mr. Gary J. Socola
Director of Quality Assurance & Sterilization Projects
SPS Medical Supply Corporation
6789 West Henrietta Road
Rush, New York 14543

Re: K020409
Trade/Device Name: STEAMplus™ Sterilization Test Pack
Regulation Number: 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: May 2, 2002
Received: May 3, 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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): _____

Device Name: STEAM*Plus*™ Sterilizer Test Pack

Indications For Use:

The SPSmedical STEAM*Plus*™ Sterilizer Test Pack is indicated for use in routine and challenge testing of steam sterilization cycles in both gravity displacement and prevacuum steam sterilizers.

(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)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020409