APR 7 2005

K050664

Attachment 4
510(k) Summary

Prepared on February 7, 2005

Submitter: Getinge USA, Inc.
1777 East Henrietta Rd.
Rochester, NY 14623 USA

Contact Person: Barb Smith, Operations Manager Consumable Products
Telephone: 585-214-6005 FAX: 585-272-5271

Trade Name: SPOR-TEST PA Biological Indicator Kit

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

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

Device Description:

The SPOR-TEST PA Biological Indicator Kit is exclusively intended to monitor the Steris® System 1 peracetic acid sterilization process, with Steris 20 sterilant. The product contains chromatography strips that are inoculated with Geobacillus stearothermophilus spores at a nominal population of 10^5 per strip. Sterile tubes of Getinge Culture Media (modified soybean casein digest broth) and a transfer clip are included. The product is intended to be used in an identical manner as the Steris® Process Biological Indicator Kit.

Intended Use:

The SPOR-TEST PA Biological Indicator Kit is only intended to monitor the Steris System 1 liquid chemical sterilization system, with Steris 20 sterilant. Use in monitoring other sterilization processes is contraindicated. SPOR-TEST PA Biological Indicators are qualified using Getinge Culture Media. When tested at 1000 ppm peracetic acid, 50°C, the SPOR-TEST PA Biological Indicator will survive at 41 seconds and will be killed at 6 minutes.

Comparison to Unmodified Device:

The SPOR-TEST PA Biological Indicator Kit's manufacturing material, manufacturing methods and storage conditions are the same as the Castle SPOR-TEST PA Biological Indicator Kit (K020205). The only change is to reduce the incubation time from 3 days (72 hours) to 2 days (48 hours). Testing per Premarket Notifications [510(k)] for Biological indicators Intended to Monitor Sterilizers Used in Health Care Facilities; Draft Guidance for Industry and FDA Reviewers Appendix H found greater than 97% assurance for a 48 hour readout.

Description of Testing:

Samples from a minimum of 3 different lots of SPOR-TEST PA were tested according to the Premarket Notifications [510(k)] for Biological indicators Intended to Monitor Sterilizers Used in Health Care Facilities; Draft Guidance for Industry and FDA Reviewers Appendix H. Results provided greater than 97% assurance for 48 hour incubation time for all lots tested per CDRH Guidelines.

Conclusion:

The SPOR-TEST PA Biological Indicator Kit is equivalent to the Castle SPOR-TEST PA Biological Indicator Kit (K020205) for monitoring Steris System 1 peracetic acid sterilization process with Steris 20 Sterilant with the improvement of results available in 48 hours.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2005

Ms. Barb Smith
Operations Manager
Getingc USA, Incorporated
1777 East Henrietta Road
Rochester, New Jersey 14623-3133

Re: K050664
Trade/Device Name: SPOR-TEST PA Biological Indicator Kit
Regulation Number: 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: March 11, 2005
Received: March 15, 2005

Dear Ms. Smith:

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

Attachment 2
Indications for Use Statement

510(k) Number: K050664

Device Name: **SPOR-TEST PA Biological Indicator Kit**

Indications for Use:

The SPOR-TEST PA Biological Indicator Kit is only intended to monitor the Steris System 1 liquid chemical sterilization system, with the Steris 20 sterilant. Use in monitoring other sterilization processes is contraindicated.

SPOR-TEST PA Biological Indicators are qualified using Getinge Culture Media. When tested at 1,000 ppm peracetic acid, 50°C, the SPOR-TEST PA Biological Indicator will survive at 41 seconds and will be killed at 6 minutes.

Prescription Use_____ AND/OR Over-The-Counter Use_X_
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature] 4/7/05

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

510(k) Number K050664