K082756

510(k) Summary

OCT 21 2009

510(k) Notification
ProTest – Steam Biological Indicator

Submitted by:	Raven Biological Laboratories 8607 Park Drive Omaha, NE 68127
Contact:	Wendy Royalty-Hann Quality Assurance/Regulatory Affairs Manager Or Robert V. Dwyer, Jr. President Phone: (402) 593-0781 Fax: (402) 593-0921
Prepared on:	
Device:	Trade name: ProTest – Steam Biological Indicator Common name: Self-contained Biological Indicator for Steam
Classification:	Class II
Predicate Device:	ProTest Steam (K041386)

DESCRIPTION

The biological indicator consists of a self-contained unit that includes bacterial spores of *Geobacillus stearothermophilus* ATCC #7953 inoculated onto a paper filter carrier and a small glass ampoule containing modified Tryptic Soy Broth with Bromocresol Purple acting as a pH indicator encased in a plastic vial that serves as the culture tube. ProTest – Steam is intended for use in 10 minute 132°C gravity displacement and 3 minute 132°C flash gravity displacement cycles.

OPERATIONAL PRINCIPALS

The ProTest – Steam Biological Indicator is placed with a load in the sterilization chamber and subjected to a normal steam sterilization cycle. The unit is then removed

and activated by crushing the glass media ampoule inside. The processed unit and an unprocessed (control) unit are incubated at 55-60°C for 24 hours.

During incubation, the available food supply (Tryptic Soy Broth) and temperature promote growth of any viable spores. As viable spores germinate and consume the provided nutrients waste products are released, increasing the acidity of the media which lowers the pH and causes a color change from purple to yellow.

Evidence of growth by color change and/or turbidity within 24 hours should be interpreted as a failure to meet the conditions necessary for sterilizations, provided signs of growth are present in the control unit.

STATEMENT OF SIMILARITY TO LEGALLY MARKETED PREDICATE DEVICE

The subject device ProTest – Steam is identical in composition and function to the legally marketed predicate device ProTest – Steam. This submission is to expand the label claims for the device to include 132°C gravity/flash gravity cycles.

- Both are intended for use in monitoring steam sterilization cycles
- Utilize the same strain of bacterial spores.
- Utilize the same carrier material.
- The same size and shape.
- Activated in the same manner.

DESCRIPTION OF TESTING

Testing was performed in accordance with AAMI/ISO 11138-1:2006 to validate the labeled claims and performance characteristics of ProTest – Steam.

Three separate lots of product manufactured from three different primary spore crops were tested for resistance, spore population, effectiveness in high temperature gravity cycles, recovery of low numbers of injured spores, and a reduced incubation period of 24 hours. For all lots tested, the above parameters and overall effectiveness in monitoring routine steam sterilization cycles has been demonstrated.

STATEMENT OF SAFETY AND EFFECTIVENESS

Based on the similar claims, design and results from the above mentioned testing, the ProTest – Steam Biological Indicator has been demonstrated to be substantially equivalent to and therefore, as safe and effect as, the legally marketed device ProTest – Steam.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ms. Wendy Royalty-Hann
Director of Quality and Regulatory Affairs
Raven Biological Laboratories, Incorporated
8607 Park Drive
Omaha, Nebraska 68127

OCT 21 2009

Re: K082756
Trade/Device Name: Raven ProTest - Steam
Regulation Number: 21CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: June 25, 2009
Received: October 2, 2009

Dear Ms. Royalty-Hann:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson for

Susan Runner, D.D.S., M.A.
Acting 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

510(k) Number

Device Name Raven ProTest – Steam

Indications for Use Raven ProTest – Steam is a self-contained Biological Indicator inoculated with *Geobacillus stearothermophilus* spores and is intended for monitoring the efficacy of steam sterilization cycles (10 minute 132°C gravity displacement and 3 minute 132°C flash gravity displacement cycles). Raven ProTest has a validated reduced incubation time of 24 hours.

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)

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

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