

VII. SUMMARY OF " PROSPORE 2[®] SELF CONTAINED BIOLOGICAL INDICATOR" FOR ETHYLENE OXIDE

1C994381

Submitter: Raven Biological Laboratories, Inc.
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President

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Prepared on: November 10, 1999

Device name: ProSpore2[®] self-contained biological indicator

Classification: Class II medical device, General hospital

Predicate Devices (legally marketed): Attest[™]

Predicate Device 510 (k) number:

DESCRIPTION:

ProSpore2[®] is a self-contained biological indicator used for determining the efficacy of an Ethylene Oxide sterilization cycle. ProSpore2[®] is comprised of a plastic tube housing with a plastic cap. Inside of the tube is a 1.2 - 1.5 ml glass ampoule of growth media consisting of Tryptic Soy Broth (soybean casein digest) and a pH indicator - bromothymol blue. Also inside of the tube housing is a paper spore disc impregnated with a population of 10⁶ *Bacillus subtilis* spores (ATCC #9372).

OPERATIONAL PRINCIPLES:

The plastic cap of the ProSpore2[®] vial has short 'tines' along its lower edge. When placed on the plastic tube body, the space between the tines allows for the passage of Ethylene Oxide into the tube and to the spore disc. A ProSpore2[®] unit is placed inside of the sterilizer along with a load to be sterilized. If all parameters are met for the cycle (sterilant concentration, relative humidity, exposure time and temperature), the EtO entering the ProSpore2[®] capsule will be sufficient to deactivate or kill the spores on the paper disc. Once the cycle is finished, the ProSpore2[®] vial is

removed from the sterilizer and sealed by depressing the cap. The sides of the plastic tubes are squeezed which will result in crushing the glass of the media ampoule. With this done, the spore disc is now in contact with the recovery media and the ProSpore2[®] unit can be placed in an incubator and incubated at 30 to 35°C for 48 hours. If the spores were killed in the sterilization cycle, the color of the recovery media will not change. If the cycle failed to kill the spores, the recovery media will change color from green to yellow, indicating growth, and a failed cycle.

The change in color is the result of 'viable' spores germinating and consuming the nutrients provided in the growth media. This consumption process involves the release of nitrogen waste products. This lowers the pH of the media and increases the acidity, which causes the color to change from green to yellow. Detection of failed EtO sterilization cycles is facilitated by the use of ProSpore2[®]. The outer label of the ProSpore2[®] plastic tube body has a chemical indicator on the label which changes color when exposed to EtO thus making it easy to distinguish processed from unprocessed vials.

STATEMENT OF SIMILARITY TO LEGALLY MARKETED PREDICATE DEVICE

ProSpore2[®] is similar in composition and function to the 'Legally Marketed Predicate Device' - Attest[™].

- Both devices are intended for use in monitoring Ethylene Oxide sterilization cycles.
- Both devices utilize a USP recommended strain of *B. subtilis* bacterial spore as its organism of choice for Ethylene Oxide resistance characteristics.
- Both devices use paper as the spore carrier.
- Both devices utilize a plastic vial and cap to house the spore carrier and media capsule.
- Both devices contain a sealed recovery media ampoule made of glass.
- Both devices use a pH indicator in the recovery media that turns from green to yellow in color when growth is present.
- Both devices require that the recovery media ampoule be activated after sterilization by breaking the glass ampoule to release the media to come in contact with the spore carrier.
- Both devices incorporate a 'chemical indicator' on the label, which will change color when exposed to Ethylene Oxide so that exposed vials can be distinguished from unprocessed vials.

DESCRIPTION OF TESTING:

ProSpore2[®] has been tested for shelf life stability over 18 months. This testing included both D-value stability and Population stability with three separate lots of finished product ProSpore2[®] vials. The recovery media has been tested to show recovery of 'low numbers' of 'injured spores', 48-hr incubation period, and the stability of the color change when growth occurred. For all lots tested, the stability of Resistance Characteristics, Spore Population, Media Recovery, 48-hr incubation, stability of color change and overall effectiveness in monitoring routine Ethylene Oxide sterilization cycles has been demonstrated.

CONCLUSION

Raven's ProSpore2[®] is substantially equivalent in composition and function to the Legally Marketed predicate device, Attest[™], for monitoring Ethylene Oxide sterilization cycles with an incubation period of 48 hours based on the testing results and analysis of 18-month shelf-life stability data.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 30 2001

Ms. Wendy Royalty
Quality Assurance Manager
Raven Biological Laboratories, Incorporated
8607 Park Drive
Omaha, Nebraska 68127

Re: K994381
Trade Name: ProSpore2® Self-contained Biological
Indicator
Regulatory Class: II
Product Code: FRC
Dated: December 27, 2001
Received: January 5, 2001

Dear Ms. Royalty:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

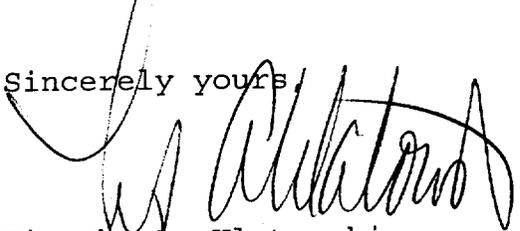
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

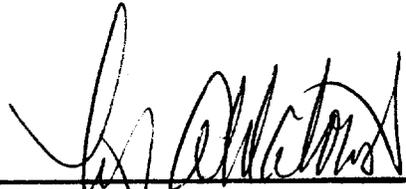


Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
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Radiological Health

Enclosure

I. INDICATION OF USE

ProSpore2 is a biological sterilization process indicator for EtO (Ethylene Oxide) sterilization. This device is intended for use by a health care provider to accompany products being sterilized through an EtO sterilization procedure and to monitor the adequacy of sterilization. The testing and validations referred to in this document were done using a 10/90 Ethylene Oxide mixture at 600 mg/L, 54°C, and with a relative humidity between 30% and 80%.



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994381