Summary of "ProSpore2 Self-contained Biological Indicator"
for steam sterilization at 121°C
510(k) # K971430

Submitter:	Raven Biological Laboratories, Inc. 5017 Leavenworth Street Omaha, Nebraska 68106 (402) 556-6690 (402) 556-4722 FAX
Contact:	Russ Nyberg Production Microbiologist
Prepared on:	3 April 1997
Device name:	ProSpore2 self-contained biological indicator
Classification:	Class II medical device, General hospital
Predicate Devices (legally marketed):	ProofPlus™ (AMSCO)
Predicate Device 510(k) number:	K915275

DESCRIPTION:

ProSpore2 is a self-contained biological indicator used for determining the efficacy of a 121°C steam sterilization cycle. ProSpore2 is comprised of a plastic tube housing with a plastic cap. Inside the tube is a 1ml glass ampoule of growth media consisting of Tryptic Soy Broth and a pH indicator of Bromocresol Purple. Also inside of the tube housing is a paper spore disc impregnated with a population of 10^5 *Bacillus stearothermophilus* spores (ATCC #7953).

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 steam into the tube and thus reaches 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 (exposure time and temperature), the steam 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 the cap is pressed down with one's thumb. This seals the vial. After allowing the unit to cool for 10 to 15 minutes, 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 55 to 60°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 was a "failed cycle" and failed to kill the spores, the recovery media will change color from purple to yellow indicating growth.

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, which increases the acidity of the media, thus lowering the pH and causing the color to change from purple to yellow. Detection of failed steam 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 saturated steam at 121°C, 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" ProofPlus.

- both devices are intended for use in monitoring steam sterilization cycles at 121°C
- both devices utilize a USP recommended strain of *B. stearothermophilus* bacterial spore as its organism of choice for steam resistance characteristics
- both devices use a paper disc as the spore carrier
- both devices utilize a plastic vial and cap to house the spore disc and media capsule
- both devices contain a sealed recovery media ampoule made of glass
- both devices use a pH indicator in the recovery media which turns to yellow 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 disc
- both devices incorporate a "chemical indicator" on the label which will change color when exposed to steam at 121°C so that exposed vials can easily be distinguished from unprocessed vials.

DESCRIPTION OF TESTING:

ProSpore2 has been tested for Population Stability over an 18-month shelf life. This testing included both D-value stability and Population stability with three separate lots of finished product Prospore2 units. Three lots were tested according to the FDA guidelines for validation of reduced incubation. A 48-hour reduced incubation was validated based on the testing results. The recovery media has been tested to show stability in the recovery of low numbers of injured spores over the 18-month shelf life and the stability of the color change when growth occurred. For all lots tested, the

stability of the Resistance Characteristics, Spore Population, Media Recovery and overall effectiveness in monitoring routine steam sterilization cycles has been demonstrated.

CONCLUSION:

Raven's ProSpore2 is substantially equivalent in composition and function to the legally marketed predicate device, AMSCO's ProofPlus, for monitoring steam sterilization cycles at 121°C, based on the testing results and analysis of 18-month shelf life stability data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 1997

Mr. Russ Nyberg
Production Microbiologist
Raven Biological Laboratories, Incorporated
5017 Leavenworth Street
Omaha, Nevada 68106

Re: K971430
Trade Name: Prospore II
Regulatory Class: II
Product Code: FRC
Dated: April 14, 1997
Received: April 17, 1997

Dear Mr. Nyberg:

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 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 (Premarket 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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" (21 CFR 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/dsmamain.html".

Sincerely yours,

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

Enclosure

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510(k) Number (if known):_____

Device Name: ProSpore

Indications For Use:

ProSporeII® is a biological sterilization process indicator for steam sterilization at 121°C is a device intended for use by a health care provider to accompany products being sterilized through a steam sterilization procedure and to monitor adequacy of sterilization.

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K971430

Prescription Use_____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)