SEP 1 3 1999

K972708

510(k) Summary
Endo-Spor Plus™/Hyprocide™ Liquid Chemical Germicide
Date Prepared: September 1, 1999

1. SUBMITTER NAME AND ADDRESS

John R. Scoville, Jr.
Cottrell, Ltd.
7399 South Tucson Way
Englewood, CO 80112
(303) 799-9401

2. DEVICE NAME

Proprietary Name:	Endo-Spor Plus™/Hyprocide™
Common/Usual Name:	Liquid Chemical Germicide
Classification Name:	Liquid Chemical Germicide

3. PREDICATE DEVICES

Omnicide and Procide 14 N.S. sterilants/disinfectants (K932922), manufactured by Cottrell, Ltd.; Cidex liquid chemical sterilants/disinfectants (K923744, K924334, K924434), manufactured by Johnson & Johnson; STERIS 20 (K875250), manufactured by STERIS Corporation.

4. INTENDED USE

Endo-Spor Plus™ liquid chemical germicide is intended for the disinfection and sterilization of endoscopic instruments and other heat labile medical and dental instruments.

5. DEVICE DESCRIPTION

The liquid chemical germicide Endo-Spor Plus™ contains the active ingredients hydrogen peroxide and peracetic acid. The germicide can be used as a high level disinfectant with a contact time of 15 minutes at 20°C under reuse conditions of up to 14 days.

6. TECHNOLOGICAL CHARACTERISTICS

Endo-Spor Plus™ liquid chemical germicide contains 7.35% hydrogen peroxide and 0.23% peracetic acid. While the active ingredients are different than that of the predicate devices, which contain glutaraldehyde (Cidex, Omnicide) or peracetic acid (STERIS 20), the microbicidal efficacy of all these liquid chemical germicides is attributed to the inactivation of cellular metabolic enzymes and transport mechanisms.

Like the predicate devices, the microbicidal efficacy of Endo-Spor Plus™ increases with contact time. Endo-Spor Plus™ can be used for high level disinfection with a contact time of 15 minutes at 20°C. The contact times required for high level disinfection and sterilization of the Endo-Spor Plus™ are less than those of the predicate devices due to the synergistic effect of the active ingredients.

7. PERFORMANCE TESTING

All performance testing was conducted in the presence of 5% calf serum or with Endo-Spor Plus™ solution which was stressed for 46 days using EPA Use-Reuse Stressing Protocol using solutions at or close to the expiration date and at the end of the reuse period. Tuberculocidal efficacy of the germicide solution was evaluated using a number of test methods. The test methods and a summary of results are presented in Table A.

Table A
Microbicidal Efficacy Testing

Test Method	Test Organisms(s)	Results
AOAC Sporicidal Test	*Bacillus subtilis* *Clostridium sporogenes*	Meets sporicidal efficacy requirements
Simulated Use Test	*Mycobacterium bovis* *Clostridium sporogenes*	Meets efficacy requirements
Quantitative Tuberculocidal Test	*Mycobacterium bovis*	Stressed solution is tuberculocidal
AOAC Use Dilution Test	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Salmonella choleraesius*	Stressed solution is bactericidal
EPA Virucidal Testing (DIS/TSS-7, November 1981)	*Herpes Simplex I* *Poliovirus Type II* *Human Immunodeficiency Virus Type I*	Stressed solution is virucidal
AOAC Fungicidal Test	Trichophyton mentagrophytes	Stressed solution is fungicidal

Simulated use testing was conducted using the insertion tubes and air water channels of flexible fiberoptic endoscopes which were contaminated in the insertion tubes with $>10^6$ cfu/ml of *M. bovis* or *C. sporogenes*. The results showed a 6-log reduction in *M. bovis* on both interior and exterior surfaces after a 15-minute contact time at 20°C and a 6-log reduction of *C. sporogenes* after 180 minutes contact at 20°C.

Clinical testing was conducted on 15 flexible fiberoptic endoscopic retrograde cholangiopancreatography (ERCP) endoscopes with elevator channels. Endoscopes were immersed in Endo-Spor Plus™ for 5 minutes at 20°C. Results showed no surviving microorganisms on any of the endoscopes tested.

The results of the microbicidal efficacy, simulated use and clinical testing demonstrate that the liquid chemical germicide Endo-Spor Plus™ is safe and effective for the disinfection and sterilization of endoscopic instruments at the temperatures and contact times specified.

Residue testing was performed on a series of Olympus endoscopes to quantitate any residual hydrogen peroxide and/or peracetic acid remaining after residue reduction had been performed. The rinse water and the exposed surfaces of the endoscopes were tested. The results showed no detectable hydrogen peroxide or peracetic acid recovered in the rinse water or on the endoscope surfaces.

Testing was performed to determine the potential toxicological affects of exposure to Endo-Spor Plus™ liquid chemical germicide. The individual tests performed and the results are summarized in Table B.

Table B.
Toxicological Evaluation of Endo-Spor Plus™

Toxicology Test	Results
Primary Dermal Irritation	Non-irritating
Acute Dermal Toxicity	Dermal LD_{50}>2 g/kg body weight
Ocular Irritation	Irreversible Irritation
Acute Oral Toxicity	Oral LD_{50}>5 g/kg body weight
Skin sensitization	Non-sensitizing
Mutagenicity (Ames test)	Non-mutagenic

The results of the toxicity testing showed Endo-Spor Plus™ to be non-toxic and not a dermal irritant. However, there was evidence of irreversible ocular irritation 2 of the 6 rabbits tested. A warning has been included in the labeling recommending use of personnel protection equipment to protect face, eyes, and hands.

The material compatibility of the Endo-Spor Plus™ liquid chemicals germicide was evaluated by subjecting a variety of metallic, plastic and rubber endoscope components to 1500 simulated cleaning cycles, which is equivalent to 2000, 15 minute high level disinfection cycles or 166, 180 minute sterilization cycles at 20°C. The samples were inspected for weight change, visible evidence of damage or any other change in appearance. The results were compared with those obtained from an identical set of endoscope components where tap water was substituted for Endo-Spor Plus™ in the solution used for the 1500 simulated cleaning cycles. The data indicates that the Endo-Spor Plus™ does not produce any corrosion or other visible damage in endoscope components. Color changes were noted on anodized aluminum parts in both the Endo-Spor Plus™ and water tests.

A separate evaluation was performed to determine the effects of Endo-Spor Plus™ on a number of different adhesives used in the manufacture of flexible endoscopes. Adhesives were applied to aluminum and polypropylene and their appearance, flexibility and adhesion tested after prolonged immersion in Endo-Spor Plus™ or tap water at temperatures of 20-63°C. The results show reduced adhesion at elevated temperatures in samples from both the Endo-Spor Plus™ and tap water tests, suggesting that the effect was due to elevated temperature rather than the Endo-Spor Plus™ solution itself.

CONCLUSION

Endo-Spor Plus™ is substantially equivalent to the listed predicate products when Endo-Spor Plus™ is used in accordance with its label instructions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 3 1999

Mr. Jack Scoville
Vice President
Cottrell. Limited
7399 South Tucson Way
Englewood, Colorado 80112

Re: K972708
Trade Name: Endo-Spor Plus/Hyprocide
Regulatory Class: Unclassified
Product Code: MED
Dated: April 15, 1999
Received: April 15, 1999

Dear Mr. Scoville:

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 (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 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
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972708

Device Name: Endo-Spor Plus™/Hyprocide™

Indications For Use:

Endo-Spor Plus™/Hyprocide™ is a chemical disinfecting and sterilization solution for use on flexible lensed endoscopy instruments, inhalation therapy equipment and instruments and materials that cannot be heat sterilized.

(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 K972708

— OVER THE COUNTER DEVICE

(Optional Format 3-10-98)