K960513

PERACT™ 20 LIQUID STERILANT/DISINFECTANT AND PERACT™ 20 INDICATOR TEST STRIPS

OCT - 1 1997

510(k) Summary of Safety and Effectiveness

Minntech Corporation, 14605 28th Ave. N, Mpls, MN 55447
Telephone: 800-328-3345
Official Contact: Robert Johnson
Vice President, Regulatory Affairs and Quality Assurance

Minntech Corporation has provided the following information to the U.S. Food and Drug Administration to support that Peract™ 20 Liquid Sterilant/Disinfectant is substantially equivalent to other sterilants currently in commercial distribution in the United States.

1. Device Description

Peract™ 20 Liquid Sterilant/Disinfectant is a single component germicide which does not require mixing or activation. The product is used full strength, without dilution. It is packaged in one gallon polyethylene bottles and has a one year shelf life.

The active ingredient in Peract™ 20 are peracetic acid and hydrogen peroxide. As discussed in Block's[1] article, the mechanism of microbial action is believed to be oxidizing sulfhydryl and sulfur bonds in proteins and enzymes, particularly in the cell walls.

Peract™ 20 Peracetic Acid Indicator Test Strips are provided to verify that the minimum effective concentration (MEC) (500 ppm peracetic acid) of Peract™ 20 is present. Three test strips are used with each application.

2. Intended Use

Peract™ 20 Liquid Sterilant/Disinfectant is intended for sterilization or high level disinfection of medical and surgical instruments that require submersion.

Peract™ 20 Liquid Sterilant/Disinfectant should be used only with heat sensitive medical and surgical instruments that are not compatible with other sterilization or high level disinfection processes that can be biologically monitored.

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[1] Block, Seymour S., Disinfection, Sterilization and Preservation; Chapter 9 Peroxygen Compounds (pages 167-181), Lea & Febiger, 1991.

Peract™ 20 Liquid Sterilant/Disinfectant should be used under the following contact conditions:

	Time	Temperature	Minimum Effective Concentration Peracetic Acid
Sterilization	8 hours	68°F (20°C)	500 ppm
High Level Disinfection	25 minutes	68°F (20°C)	500 ppm

3. Comparison to another Device in Commercial Distribution within the United States:

Peract™ 20 Liquid Sterilant/Disinfectant is comparable in its intended use to other liquid sterilants currently on the market in the U.S. Peract™ 20 is similar in use and product claims to Cottrell's ProCide® NS and Johnson & Johnson's Cidex®.

4. Summary

Minntech Corporation has performed testing to demonstrate that Peract™ 20 Liquid Sterilant/Disinfectnat and Peract™ 20 Indicator Test Strips are safe and effective when used according to the respective instructions for use.

4.1 Efficacy Testing

The following efficacy testing was performed on Peract™ 20 with all of the following conditions: at the minimum of its specifications, at the end of its shelf life, stressed to the end of its 14 day reuse period and at its MEC (500ppm PAA). The testing showed the product to be sporicidal, tuberculocidal, virucidal, fungicidal, and bactericidal.

AOAC sporicidal testing was performed on three lots of Peract™ 20 with the above noted conditions. Sporicidal simulated use testing was also performed on endoscopes to show efficacy as a sterilant on actual devices.

Tuberculocidal testing was performed on three lots of Peract™ 20 with the above noted conditions. Tuberculocidal simulated use testing was also performed on endoscopes to show efficacy as a high level disinfectant on actual devices.

Peract™ 20 was determined to be virucidal when tested against Poliovirus Type 2, Influenza A_2 , Human Immunodeficiency Virus Type 1, and Herpes Simplex Virus Type 1. Peract™ 20 was considered fungicidal when tested against *Trichophyton mentagrophytes*. Use dilution testing showed the efficacy of Peract™ 20 against *Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa.*

Clinical testing of used scopes further supports the efficacy of the germicide when used under the instructions of the directions for use. Testing determined residues of Peract™ 20 remaining on endoscopes after sterilization/disinfection and rinsing were not significant.

4.2 Biocompatibility Testing

Standard patient toxicity testing evaluated the effect of residues, cytotoxicity, hemolysis, acute toxicity, and vaginal (mucosal membrane) irritation.

All biocompatibility testing demonstrated that Peract™ 20 is safe for the patient when used according to the instructions for use.

4.3 Material Compatibility

Material compatibility testing demonstrates that Peract™ 20 can be used with a wide range of materials and endoscopes. Testing included soaking and cycling common materials and endoscopes for the estimated lifetime of the items.

Material compatibility testing demonstrated that Peract™ 20 is compatible with the materials and devices listed when used according to the instructions for use.

4.4 Stability

Peract™ 20 has a shelf life of one year. Stability studies were performed according to section (III)(F)(3) of the Liquid Chemical Germicide Document. Studies demonstrated that the chemical and physical stability of Peract™ 20 were within specifications at the expiration date.

4.5 Test Strips

Peract™ 20 Indicator Test Strips demonstrated to consistently and accurately test the germicide at its minimum effective concentration of 500 ppm peracetic acid when three test strips were used.

Testing of the indicator strips was accomplished by showing: the efficacy of the strips when they were exposed to Peract™ 20; that they were stable over the labeled shelf life; and were stable in the opened bottle for 30 days. All of these tests were performed on a minimum of three lots of strips using Peract™ 20 diluted to various concentrations of PAA from much lower to much higher than the MEC of 500ppm PAA. The testing was also performed on solutions close to the MEC of 500ppm PAA to ensure the strips performed appropriately at concentrations around the MEC. The results of the testing showed the strips

performed appropriately when three strips were used as called out in the directions for use.

5.0 Summary of Substantial Equivalence

Minntech Corporation has provided the above information within the 510(k) to support that Peract™ 20 Liquid Sterilant/Disinfectant and Peract™ 20 Indicator Test Strips are safe and effective when used according to the respective directions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Ms. Lynn Lueders
Director, Regulatory Affairs
Minntech Corporation
14605 28th Avenue, North
Minneapolis, Minnesota 55447

OCT - 1 1997

Re: K960513
Trade Name: Peract™20 Liquid Sterilant/Disinfectant
Regulatory Class: Unclassified
Product Code: MED
Dated: July 14, 1997
Received: July 15, 1997

Dear Ms. Lueders:

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 current Good Manufacturing Practice requirement, 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) 594-4618. 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

Indications for Use

510(k) Number (if known): K960513

Device Name: Peract™ 20 Liquid Sterilant/Disinfectant and Peract™ 20 Indicator Test Strips

Intended Use:

Peract™ 20 Liquid Sterilant/Disinfectant is intended for sterilization or high level disinfection of medical and surgical instruments that require submersion.

Peract™ 20 Liquid Sterilant/Disinfectant should be used only with heat sensitive medical and surgical instruments that are not compatible with other sterilization or high level disinfection processes that can be biologically monitored.

Peract™ 20 Liquid Sterilant/Disinfectant should be used under the following contact conditions:

	Time	Temperature	Minimum Effective Concentration Peracetic Acid
Sterilization	8 hours	68°F (20°C)	500 ppm
High Level Disinfection	25 minutes	68°F (20°C)	500 ppm

Peract™ 20 Indicator Test Strips are intended for verifying the minimum effective concentration of peracetic acid in Peract™ 20 Liquid Sterilant/Disinfectant during reuse.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __ OR Over-the counter use X
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K960513