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A. 510(K) SUMMARY

1. 510(k) Summary of Safety and Effectiveness

Contact	Neelu Medhekar R.A.C., Project Manager, Regulatory Affairs Phone: 949 789 3838 Fax: 949 789 3900 Advanced Sterilization Products Division of Ethicon Inc. 33 Technology Drive Irvine, Ca 92618
Date	September 22, 2003
Device name	Classification: Liquid chemical germicide Trade Name: CIDEX® OPA Concentrate Proprietary Name: 5.75% nominal *ortho*-phthalaldehyde Solution
Legally marketed device	CIDEX® OPA Concentrate In-Use solution claims equivalence to the following legally marketed medical devices: CIDEX® OPA Solution (K991487) and Steris 20™ Sterilant/ Steris System 1™ (K875280)
Device description	CIDEX® OPA Concentrate is formulated to contain 5.75% w/v of *ortho*-phthalaldehyde. The resultant solution contains a corrosion inhibitor, a chelating agent, and a dye in a phosphate buffer. *ortho*-Phthalaldehyde is chemically related to glutaraldehyde in that they are both aldehydes. The mechanism of action of *ortho*-phthalaldehyde is postulated to be similar to glutaraldehyde and is based on powerful binding of the aldehyde to the outer cell wall of the organism.

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Intended use	CIDEX® OPA Concentrate is intended for use as a high level disinfectant for reprocessing heat sensitive (<60°C) endoscopes. CIDEX® OPA Concentrate is intended for use only in the washer/disinfector, the EvoTech System.. This product is not intended for manual use or in automatic endoscope reprocessors that re-use their high level disinfectant.
Performance data	High level disinfectant: CIDEX® OPA Concentrate is a high level disinfectant at its In-Use concentration when used according to the Directions for Use
Efficacy Testing	CIDEX® OPA Concentrate In-Use solution was tested using the standard array of microbiology tests for germicidal efficacy. Tests demonstrated sporicidal, bactericidal, fungicidal, tuberculocidal and virucidal efficacy of CIDEX® OPA Concentrate In-Use solution. The CIDEX® OPA Concentrate used within the test protocols represented oldest available product. Simulated Use: Simulated use testing prior to cleaning, exposure to CIDEX® OPA Concentrate In-Use solution resulted in a >6 Log_{10} reduction of *Mycobacterium terrae* when flexible endoscopes were contaminated with cells and artificial soil. The diluted CIDEX® OPA Concentrate at an MEC of 0.055% concentration at 50° C is effective against *Mycobacterium terrae* in artificial soil. In-Use Testing: Endoscopes used in a clinical setting were subjected to high level disinfection without cleaning. Sterility testing showed no growth on all endoscope surfaces and channels after reprocessing in CIDEX OPA Concentrate In Use solution.

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Biocompatibility	CIDEX® OPA Concentrate and the In-Use solution were evaluated for biocompatibility. The active ingredient and the formulated product were subjected to a panel of toxicological tests, including acute oral and dermal toxicity, skin sensitization, genetic toxicity, *in vitro* and *in vivo* systems, subchronic oral toxicity and developmental toxicity tests. All animal toxicity data indicate that the product is at least as safe for human use as the predicate device. Biocompatibility of product residues testing was conducted. Results indicate that CIDEX® OPA Concentrate In-Use solution residuals absorbed onto materials commonly used in reprocessed medical devices are at levels well below those, which cause toxic effects in animals.
Material compatibility	CIDEX® OPA Concentrate and the In-Use solution were evaluated for effects on materials commonly used to fabricate washer/disinfectors and medical devices. The results showed minimal effect on test articles and were similar to those seen with the predicate device.
Stability	CIDEX® OPA Concentrate was tested and found stable for 15 months at 15-30° C. The in machine use life is 80 days.
Conclusion	The data presented and the equivalence demonstrated to the predicate device support the claim of substantial equivalency for CIDEX® OPA Solution. CIDEX® OPA Concentrate In Use solution is safe and effective as a high level disinfectant when used as labeled for reprocessing semi-critical medical devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 4 2005

Advanced Sterilization Products
Ms. Neelu Medhekar
Project Manager, Regulatory Affairs
Ethicon, Incorporated
33 Technology Drive
Irvine, California 92618

Re: K032959
Trade/Device Name: CIDEX OPA Concentrate
Regulation Number: 880.6885
Regulation Name: Liquid Chemical Sterilants High Level Disinfectants
Regulatory Class: II
Product Code: MED
Dated: March 16, 2005
Received: March 17, 2005

Dear Ms. Medhekar:

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.

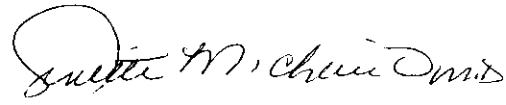
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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

510(k) Number (if known): K032959

Device Name: CIDEX® OPA Concentrate

Indications For Use:

CIDEX® OPA Concentrate is a high level disinfectant (HLD) at the minimum IN USE concentration of 0.055% with a contact time of 5 minutes at 50°C for reprocessing heat sensitive (<60°C) semi-critical endoscopes when used according to the Directions for Use.

CIDEX® OPA Concentrate is intended for use in the ASP EvoTech™ System. THIS PRODUCT IS NOT INTENDED FOR MANUAL USE. See Directions for Use.

_____Prescription Use _____ AND/OR Over-The-Counter Use √
(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
510(k) Number K032959