FEB 2 7 2003

N. 510(K) SUMMARY

1. 510(k) Summary of Safety and Effectiveness K030004

a. CONTACT

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Project Manager, Regulatory Affairs
(949) 789-3838 (Telephone)

Advanced Sterilization Products
Division of Ethicon Inc.
33 Technology Drive
Irvine, Ca 92618

b. DATE

December 26, 2002

c. DEVICE NAME

Classification: Liquid chemical germicide

Trade Name: CIDEX® OPA Solution

Proprietary Name: 0.55% *ortho*-phthalaldehyde Solution

d. LEGALLY MARKETED DEVICE

CIDEX® OPA Solution claims equivalence to the following legally marketed medical device: CIDEX® OPA Solution (K991487).

e. DEVICE DESCRIPTION

CIDEX® OPA Solution is formulated to contain 0.55% w/v of *ortho*-phthalaldehyde. The resultant solution contains a corrosion inhibitor, chelating agents, 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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f. INTENDED USE

CIDEX® OPA Solution is intended for use as a high level disinfectant for reprocessing heat sensitive medical devices.

CIDEX® OPA Solution can be used in manual systems (trays and buckets) and automated endoscope reprocessors.

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g. EFFICACY TESTING

CIDEX® OPA Solution was tested for sporicidal and mycobactericidal efficacy using a disinfection cycle of 5 minutes at 25°C. The efficacy testing was performed with reused CIDEX® OPA Solution. Data generated on the microbiological efficacy of *ortho*-phthalaldehyde employed concentrations at or below the **minimum effective concentration (MEC) of 0.3%.**

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h. BIOCOMPATIBILITY

Biocompatibility evaluation of product residues was conducted. Results indicate that CIDEX® OPA Solution residuals absorbed onto materials commonly used in reprocessed medical devices are at levels well below those, which cause toxic effects in animals.

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i. MATERIAL COMPATIBILITY

CIDEX® OPA Solution was evaluated for its effect on functionality and compatibility with endoscopes commonly used in medical facilities at 25°C in an AER (that can be set to 25°C). No functional or compatibility issues were found.

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j. STABILITY

CIDEX® OPA Solution was tested and found stable for 24 months at 15-30° C.

k. CONCLUSION

The data presented and the equivalence demonstrated to the predicate device support the claim of substantial equivalency for CIDEX® OPA Solution. CIDEX® OPA Solution is safe and effective as a high level disinfectant when used as labeled for reprocessing heat sensitive medical devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Neelu Medhekar
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Advanced Sterilization Products
A Johnson & Johnson /Div. of Ethicon, Inc
33 Technology Drive
Irvine, California 92618

Re: K030004
Trade/Device Name: CIDEX® OPA Solution
Regulation Number: 880.6885
Regulation Name: Liquid Chemical Ssterilants
Regulatory Class: II
Product Code: MED
Dated: December 31, 2002
Received: January 2, 2003

Dear Mr. 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 (301) 594-4618. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ADVANCED STERILIZATION PRODUCTS℠
a Johnson & Johnson company
REGULATORY AFFAIRS DEPARTMENT

510(k) Number: K030004
Device Name: CIDEX® OPA Solution
Indications-For-Use:

This Premarket Notification is a modification to the previously cleared CIDEX® OPA Solution. This submission expands the cleared Indications for Use to include a 5-minute claim at 25°C for the high level disinfectant in automatic endoscope reprocessors:

High Level Disinfectant at a minimum of 25°C (77°F): CIDEX® OPA Solution is a high level disinfectant when used or reused in a legally marketed automatic endoscope reprocessor (that can be set to 25°C) according to the Directions for Use, at or above its Minimum Effective Concentration (MEC) as determined by CIDEX® OPA Solution Test Strips, with an immersion time of at least 5 minutes for a reuse period not to exceed 14 days.

The modified Indications for Use for CIDEX® OPA Solution now reads:

CIDEX® OPA Solution is a high level disinfectant for reprocessing heat sensitive medical devices, for which sterilization is not suitable, and when used according to the Directions for Use.

Manual Processing: High Level Disinfectant at a minimum of 20°C (68°F): CIDEX® OPA Solution is a high level disinfectant when used or reused, according to the Directions for Use, at or above its Minimum Effective Concentration (MEC) as determined by CIDEX® OPA Solution Test Strips, with an immersion time of at least 12 minutes for a reuse period not to exceed 14 days.

Automatic Endoscope Reprocessors that can be set to 25°C: High Level Disinfectant at a minimum of 25°C (77°F): CIDEX® OPA Solution is a high level disinfectant when used or reused in a legally marketed automatic endoscope reprocessor (that can be set to 25°C) according to the Directions for Use, at or above its Minimum Effective Concentration (MEC) as determined by CIDEX® OPA Solution Test Strips, with an immersion time of at least 5 minutes for a reuse period not to exceed 14 days.

Minimum Effective Concentration (MEC): 0.3%.

Note: If your AER cannot be set to a minimum of 25°C please follow the time and temperature stated in Indications for Use, Manual Processing.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K030004