K040883

J. SUMMARY OF SAFETY AND EFFECTIVENESS

1. 510(k) Summary of Safety and Effectiveness

Contact	Neelu Medhekar R.E.H.S., R.A.C., MAR 1 5 2005 Project Manager, Regulatory Affairs Phone: 949 789 3838 Fax: 949 789 3900 Advanced Sterilization Products Division of Ethicon Inc. a Johnson & Johnson company 33 Technology Drive Irvine, CA 92618
Date	April 2, 2004
Device name	Classification: Endoscope and accessories Trade Name: EvoTech™ System Proprietary Name: EvoTech™ Integrated Endoscope Disinfection System
Legally marketed device	The EvoTech System claims equivalence to the Medivators DSD-91 Disinfector (K914145). The predicate is a system that utilizes a sterilant / high level disinfectant solution to reprocess reusable medical devices. It regulates the contact conditions (for example temperature, concentration, appropriate rinsing) required for effective disinfection / sterilization of the devices being reprocessed.
Device description	The EvoTech™ System is a two-basin washer / disinfector utilizing a concentrated high-level disinfectant (CIDEX® OPA Concentrate – K032959) that is diluted within the system to an In-Use concentration. The system performs a leak test, a block test, pre-rinse, wash, disinfect, rinse, and alcohol flush on the endoscope being reprocessed. The disinfection temperature is 50-55°C. The In-Use disinfectant is discarded after each use by the system.
Intended use	The EvoTech™ System is intended for use as a washer / disinfector for reprocessing flexible endoscopes that do not contact normally sterile areas of the body.

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Performance data	The EvoTech System, a washer / disinfector, is indicated for use with the high level disinfectant CIDEX® OPA Concentrate, (MEC of 0.055%, minimum temperature of 50°C for a contact time of 5 minutes) to achieve high-level disinfection of flexible endoscopes. Endoscopes must be manually cleaned prior to placement in the EvoTech System. The System includes an on-board MEC monitor, performs automated leak test, block test and post processing alcohol flush.
Efficacy Testing	The EvoTech System was tested using the standard array of tests defined in the FDA Guidance on Premarket Notification [510(k)] Submission for Automated Endoscope Washers, Washer / Disinfectors, and Disinfectors Intended for Use in Health Care Facilities, august, 1993 Simulated Use Testing: The high level disinfectant indicated for use with the EvoTech System was tested for efficacy in a simulated use environment. A 6 Log_{10} reduction of *Mycobacterium terrae* was achieved when flexible endoscopes, contaminated with spores and artificial soil and were exposed to CIDEX OPA Concentrate In Use solution without cleaning. The diluted CIDEX® OPA Concentrate at an MEC of 0.055% OPA concentration at 50°C is effective against *Mycobacterium terrae* in artificial soil. In Use Testing: Endoscopes used in a clinical environment were reprocessed in the EvoTech System without manual cleaning. Sterility testing demonstrated no growth.
Biocompatibility	An endoscope reprocessed in the EvoTech System was evaluated for residue levels. The analysis indicates that the level of OPA residual remaining on an endoscope is not likely to cause toxic effects in humans.
Material compatibility	The EvoTech System using CIDEX OPA Concentrate In-Use solution was evaluated for its effect on materials commonly used in medical devices. Multiple disinfection cycles over extended periods of time resulted in minimal effect on the test articles. The effects seen were similar to those seen with the predicate device for the high level disinfectant - CIDEX OPA Solution K991487.
Stability	N / A
Conclusion	The data presented and the equivalence demonstrated to the predicate device support the claim of substantial equivalency for the EvoTech™ System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 5 2005

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

Re: K040883
Trade/Device Name: EvoTech™ Integrated Endoscope Disinfection System
Regulation Number: 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FEB
Dated: December 23, 2004
Received: December 27, 2004

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.

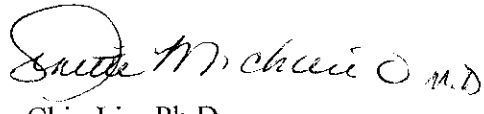
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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: K040883

Device Name EvoTech™ Integrated Endoscope Disinfection System

Indications For Use:

The EvoTech System, a washer / disinfector, is indicated for use with the high level disinfectant CIDEX® OPA Concentrate, (MEC of 0.055%, minimum temperature of 50°C for a contact time of 5 minutes) for reprocessing heat sensitive (<60°C) semi critical endoscopes. Endoscopes must be manually cleaned prior to placement in the EvoTech System.

The System includes an on-board MEC monitor, performs automated leak test, block test and post processing alcohol flush.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use ✓

(Optional Format 1-2-96)

33 Technology Drive, Irvine, CA 92618 (949) 453 6400 FAX (949) 789 3900

Sheila A Murphy RS

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