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SEP 2 1998

510 (K) SUMMARY

Device Trade Name:	MedSCI 3% glutaraldehyde
Common Name:	Sterilant/High-level Disinfectant Activated Dialdehyde Solution
Classification Name:	Unclassified, Code INCB(80) MED *Liquid Chemical Germicide*
Contact Person:	Robert McIntosh MedSCI, Inc. P.O. Box 5248 Greensboro, NC 27435 (336) 274-0149
Date Prepared:	August 20, 1998

Substantial Equivalence Statement: MedSCI 3% glutaraldehyde is substantially equivalent to the predicate J&J Cidexplus (K923744).

DESCRIPTION: MedSCI 3% glutaraldehyde is an activated glutaraldehyde liquid chemical sterilant and high-level disinfectant when used according to the Directions for Use. The active ingredient in MedSCI 3% glutaraldehyde is glutaraldehyde in a nominal concentration of 3.0%. In addition, the activated solution contains buffers, wetting agent, rust inhibitor, fragrance and a dye that changes the solution green upon activation thereby indicating readiness for use.

Intended Use:
MedSCI 3% glutaraldehyde may be used to sterilize or high-level disinfect reusable devices that are heat labile or otherwise incompatible with other biologically monitored methods of sterilization. MedSCI 3% glutaraldehyde is intended to be used by healthcare practitioners, e.g. doctors, nurses and dentists in various healthcare facilities, e.g. hospitals, doctors' offices, and dentists' offices.

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Germicidal Level of Activity for MedSCI 3% glutaraldehyde as a:

Sterilant. MedSCI 3% glutaraldehyde is a sterilant when reusable medical devices are immersed for 10 hours at 25°C. It may be used or reused for a maximum of 28 days if the glutaraldehyde concentration is above the Minimum Effective Concentration (MEC) of 1.8% as determined by the 3M Cold Sterilog® 2.1% Glutaraldehyde Monitor.

High-Level Disinfectant. MedSCI 3% glutaraldehyde is a high-level disinfectant when reusable medical devices are immersed for 25 minutes at 25° C. It may be used or reused for a maximum of 28 days if the glutaraldehyde concentration is above the Minimum Effective Concentration (MEC) of 1.8% as determined by the 3M Cold Sterilog® 2.1% Glutaraldehyde Monitor.

Determination of Substantial Equivalence:
MedSCI 3% glutaraldehyde is substantially equivalent to the predicate Sterilant/High Level disinfectant Johnson & Johnson's Cidex Plus. Both products are glutaraldehyde based and intended to be used on critical and semi-critical reusable medical devices. The similarities and differences to the predicate product are described in the comparison matrix in this section which also summarizes technological characteristics.

SUBSTANTIAL EQUIVALENCE MATRIX

Characteristic	MedSCI 3% glutaraldehyde	Cidex Plus K 923744
active ingredient	glutaraldehyde	glutaraldehyde
concentration	3.0%	3.4%
intended use	reprocess endoscopes	reprocess endoscopes
Use/reuse	up to 28 days	up to 28 days
steriliant claim	10 hours @ 25C	10 hours @ 25C
high-level claim	25 min @ 25C	20 min @ 25C
rust inhibitor	yes	yes
dilution required	no	no
activation	raise pH to alkaline	raise pH to alkaline
chemical test	3M strip	3M strip
MEC	1.8% glut	2.1% glut
Activator	powder	liquid

The determination of substantial equivalence is based on an assessment of performance conducted in the laboratory following established protocols.

Summary of Microbiological Test Data

The data included demonstrates that MedSCI 3% glutaraldehyde is substantially equivalent to the predicate liquid chemical germicide, Cidex Plus. The sporicidal and tuberculocidal tests were conducted side-by-side with the predicate product. The lab efficacy tests were conducted on 28 day stressed product at or below the minimum effective concentration of 1.8% glutaraldehyde.

Sterilization claim

The contact time of 10 hours at 25°C is supported by the AOAC Sporicidal Test. Three lots of stressed MedSCI 3% glutaraldehyde was tested against spores dried on carrier surfaces. The test results showed that all spores were eliminated and no positive cultures were observed. Confirmatory AOAC Sporicidal Test was performed on two lots of disinfectant with satisfactory results.

High-Level Disinfection Claim

The contact time of 25 minutes at 25°C is supported by the Quantitative Tuberculocidal test.

Other efficacy tests performed for vegetative bacteria, fungi and viruses are the following tests which showed satisfactory results at less than 5 minutes at 20°C:

AOAC Use Dilution Test,
AOAC Fungicidal Effectiveness Test,
Virucidal Effectiveness Test,
HIV Effectiveness Test,

An End-Point of the total kill contact time for spores was carried out to demonstrate that an adequate safety margin has been incorporated into the contact time of 10 hours at 25C.

Additional tests were performed to demonstrate effectiveness in simulated and actual use conditions.

Simulated Use Test

A simulated use test was conducted in the laboratory to support the contact condition for high level disinfection of endoscopes at 25°C for 25 minutes. The test demonstrates the effectiveness of MedSCI 3% glutaraldehyde to kill *M. Terrae* dried on flexible fiber endoscopes.

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Clinical or In-Use Test
Reprocessing flexible fiber endoscopes in use studies demonstrates the effectiveness of the disinfectant in actual use conditions. The manual reprocessing followed the ASTM 1518-94 protocol.

Stressed Test
Three lots of MedSCI 3% glutaraldehyde were stressed in order to carry out certain tests under worst case conditions. Simulated reprocessing was carried out according to an EPA "Reuse Test Protocol Specifications". Use Re-use Manual Stressing stressed the test agents and predicate product for 28 days, consistent with the maximum reuse life of the product. Chemical determinations were made of the % glutaraldehyde to verify that the stressed material was at or below the Minimum Effective Concentration.

D-Values
D-Value Comparisons, Range Finding Studies at both 20°C and 25°C were conducted to evaluate relative sporicidal activity against Bacillus spores. The D-Values were calculated and plotted graphically.

Performance testing with the Cold Sterilog® 2.1% Glutaraldehyde Monitor(1)
Testing was conducted to verify the performance of the Cold Sterilog® 2.1% Glutaraldehyde Monitor with the MedSCI 3% Glutaraldehyde. The data analysis included the characteristics of comparative sensitivity and comparative specificity. The test data demonstrates the ability of the Cold Sterilog® 2.1% Glutaraldehyde Monitor to determine that the glutaraldehyde concentration is above the Minimum Effective Concentration (MEC) of 1.8%. Additionally, the testing demonstrated that the use of the Cold Sterilog® 2.1% Glutaraldehyde Monitor provides a "margin of safety" above the Minimum Effective Concentration of 1.8%.

(1) Cold Sterilog®is a trademark of the 3M corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1998

Mr. Robert H. McIntosh
MedSCI, Incorporated
P.O. Box 5248
Greensboro, North Carolina 27435

Re: K974062
Trade Name: MedSCI 3% Glutaraldehyde
Regulatory Class: Unclassified
Product Code: MED
Dated: June 16, 1998
Received: June 17, 1998

Dear Mr. McIntosh:

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,

S. Putman for

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) K974062

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974062

Prescription Use _____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)