

JUN 5 1998

**510(k) SUMMARY
K962959**

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

Submitter's Name: HDC Medical, Inc.
707 Farmingham Road
Louisville, KY 40243 USA
Telephone: (502) 267-7873
Contact Person: Hugh Doss, President

Date of Summary: June 3, 1998

Device Name: Peracidin™ Dialyzer Reprocessing Concentrate

Device Classification: Liquid Chemical Disinfectant (80 MED)

Legally Marketed Device To Which Equivalence Is Claimed: Renalin Cold Sterilant (K882564), manufactured by Minntech Corporation, determined to be substantially equivalent to a pre-enactment device on January 9, 1989.

Device Description: Peracidin™ Dialyzer Reprocessing Concentrate is a stabilized mixture of hydrogen peroxide 27.0% and peroxyacetic acid 4.5%; inert ingredients are 68.5% (nominal concentrations). The concentrate is a clear colorless liquid, is highly acidic, and is completely soluble in water. Peracidin breaks down to acetic acid, water, and oxygen.

Intended Use: Peracidin™ Dialyzer Reprocessing Concentrate is indicated for the *in-vitro* cleaning and disinfection of hollow fiber dialyzers, classified as follows:

Conventional dialyzer, 21 CFR 876.5820, product code 78 FJI
High permeability dialyzer, 21 CFR 876.5860, product code 78 KDI

The product is intended for use only with reprocessing systems, automated or manual, that have been validated by the system manufacturer for use with peracetic acid. The intended use of Peracidin is identical to that of Renalin.

Descriptive Summary Of Technological Characteristics And Those Of Predicate Device: Both Peracidin and Renalin are stabilized mixtures of hydrogen peroxide and peroxyacetic acid. The products are liquid chemical disinfectants used for reprocessing of hollow fiber dialyzers. The concentrations of hydrogen peroxide and peracetic acid in the two products are identical. The technological characteristics of Renalin and Peracidin are identical.

Performance Data: Peroxyacetic acid (PA), the primary active ingredient in both Renalin and Peracidin, has been shown to be an effective biocidal agent. Peracetic acid-based chemical germicides have a long history of use in dialyzer reprocessing. The actions of these germicides are bactericidal, sporocidal, tuberculocidal, pseudomonacidal, virucidal, and effective against non-tuberculous mycobacteria (NTM). The decomposition products have low or no toxicity. Efficacy and other performance characteristics are well-established by extensive long-term clinical use and are well-documented in the scientific literature. The safety and effectiveness performance of Peracidin are identical to the safety and effectiveness performance of Renalin.



JUN 5 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

HDC Medical, Incorporated
C/O Ms. Lisa S. Jones
Regulatory Affairs Consultant
Devices for the Future, L.L.C.
9223 Ilona Lane
Houston, Texas 77025-4218

Re: K962959
Trade Name: Peracidin Dialyzer Reprocessing Concentrate
Regulatory Class: Unclassified
Product Code: MED
Dated: May 5, 1998
Received: May 6, 1998

Dear Ms. Jones:

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 (Pre-market 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 pre-market notification submission does not affect any obligation you might have under sections 531

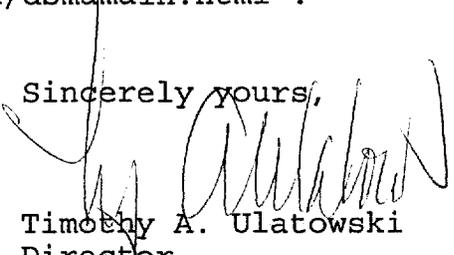
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

June 3, 1998

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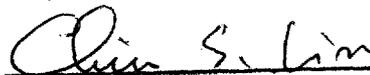
510(k) Number: K962959

Device Name: Peracidin Dialyzer Reprocessing Concentrate

Indications for Use:

Peracidin Dialyzer Reprocessing Concentrate is indicated for the *in vitro* cleaning and disinfection of hollow fiber dialyzers. The product is intended for use only with dialyzer reprocessing systems, automated or manual, that have been validated for use with peracetic acid.

(Concurrence of CDRH, Office of Device Evaluation (ODE))



(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

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Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-the-Counter Use