

AUG 14 2000



510(k) SUMMARY

1. Submitter Information:

Name: Clarigen, Incorporated
Address: 5922 Farnsworth Court, Carlsbad, California 92008
Contact Person: Edit Hegyi, M.D., Ph.D.
Phone Number: 760-929-4996
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Date Prepared: November 05, 1999

2. Device Name

Proprietary name: DialGuard™
 Common name: Filter for the removal of endotoxin from dialysate and water
 Classification name: Water Purification Subsystem per 21 CFR 876.5665
 Product Code: 78 FIP

3. Predicate Device

RenaGuard™ Dialysate Filter
 510(k) Number K945136

4. Device Description

DialGuard™ is a device used for the reduction of endotoxin from dialysate and water. It consists of a polysulfone housing filled with an affinity resin with polysulfone endcaps. The endcaps are fitted with Quick Connect couplings.

5. Indications for Use

Device	Indications for Use
DialGuard™	DialGuard™ is intended to be used to remove endotoxin from dialysate, water used to prepare dialysate, and water used to regenerate dialysers.
RenaGuard™	RenaGuard™ is intended to be used to remove bacteria and endotoxin from dialysate

6. Technological Characteristics

	DialGuard™	RenaGuard™
Case Material	polysulfone	polycarbonate
Sanitizable	yes	yes
Position on Dialyzer	Prior to artificial kidney	Prior to artificial kidney
Materials	agarose based affinity resin	hollow fiber membrane

7. Safety and Effectiveness

The following testing was conducted to support substantial equivalence as a filter to remove endotoxin from dialysate and water for dialysate:

Flow Rate
Pressure Studies
Endotoxin Removal from water and dialysate

The maintenance of Dialysate Composition through the use of:

Conductivity and Ion Composition testing
leachables testing
Biocompatibility Testing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 14 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Edit Hegyi, M.D., Ph.D.
Vice President
Research and Development
Clarigen, Inc.
5922 Farnsworth Court
Carlsbad, CA 92008

Re: K993806
DialGuard™ Endotoxin Removal Device for
treatment of dialysate and dialysis water
Dated: June 23, 2000
Received: June 26, 2000
Regulatory Class: II
21 CFR §876.5665/Procode: 78 FIP

Dear Dr. Hegyi:

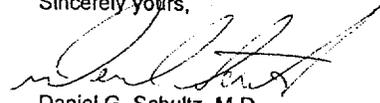
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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) 594-4591. 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,



Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

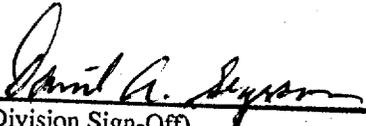
Statement of Indications for Use

The DialGuard™ device is intended to be used for the reduction of endotoxin from:

1. Dialysate prior to entering the dialyser
2. Water prior to its use for preparation of dialysate
3. Water prior to use for regenerating dialysers.

DialGuard™ is intended to be used on a regular preventative basis during hemodialysis treatments. Experimental data indicates that DialGuard™ will consistently reduce endotoxin levels to ≤ 0.05 EU/mL. (AAMI standard for water for dialysate is < 5.0 EU/mL. Currently, there are no standards set for dialysate).

Prescription Use
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993806