A.0 510(k) Summary of Safety and Effectiveness

FEB 0 6 2013

A.1 Submitter Information

Company Name and Address:	Contact Name:
Asahi Kasei Medical Company, Ltd. 1-105 Kanda Jinbocho, Chiyoda-ku, Tokyo 101-8101, Japan	Patsy J.Trisler, JD, RAC Vice President, Regulatory and Clinical Qserve America, Qserve Group B.V. 154 Main Street, Suite #2 Charlestown, NH 03603 Telephone: 301-652-5344 Fax: 509-807-7204 Email: patsy.trisler@qservegroup.com

A.2 Date Prepared: May 9, 2012

A.3 Name of Device

3.1 Trade Name: Asahi REXEED-SX/LX Series Dialyzer

3.2 Common Name: High Flux Hemodialysis Membrane Dialyzer or High Flux Hollow Fiber Dialyzer

3.3 Classification Name, Class, Product Code and Panel

Classification Name and Regulation Number	Class	Product Code	Panel
High Permeability Hemodialysis Systems, Title 21 Code of Federal Regulations § 876.5860	II	KDI	Gastroenterology and Urology

A.4 Substantial Equivalence Claimed to Predicate Device

APS/REXEED, cleared for commercial distribution via 510(k) Premarket Notifications K001250 dated August 16, 2000; K041726 dated July 23, 2004; K051187 dated June 8, 2005; and K082515, dated October 3, 2008.

A.5 Device Description

The line of Asahi REXEED-SX/LX Series Dialyzer is a family of high permeability hollow fiber dialyzers intended for the treatment of patients with acute or chronic renal failure. REXEED-SX/LX Series Dialyzer is designed for single use. REXEED-SX/LX Series Dialyzer is constructed of hollow fiber (polysulfone) membranes, housed within a plastic casing of styrene-butadiene block copolymer and are subjected to electron beam irradiation prior to shipment.

This Special 510(k) describes the following modifications:

- Manufacturing Process Change: insertion of an additional step to enhance removal of manufacturing materials.
- Labeling Change: changes to the Instructions for Use to emphasize importance of following instructions for use.
- Device Modification: change in specification limit of leakage and related physical properties of hollow fibers for safer treatment and operation.

A.6 Intended Use and Indications for Use

A. REXEED-SX/LX Dialyzers is intended for use for hemodialysis treatment of patients who have chronic or acute renal failure.
B. REXEED SX/LX Dialyzers must be used in accordance with the instructions for a physician familiar with hemodialysis and familiar with the conditions of the patient.
C. REXEED SX/LX Dialyzers have been tested *in vitro* under single use conditions.

A.7 Evaluation of Design Modifications

As the basis for Asahi's device evaluation studies and overall process for managing medical device risk, the company has performed a risk analysis using procedures based on ISO 14971(2007) "Medical Devices – Application of Risk Management to Medical Devices". The risk analysis method used to assess the impact of the modification was Failure Modes and Effects Analysis (FMEA). Design validation or where appropriate, design verification, and process validation based on the result of risk analysis and design input were performed to verify those modifications. All test results meet the acceptance criteria, and proved that those modifications to be appropriate.

A.8 Conclusion:

Asahi made modifications to the REXEED-SX/LX Series Dialyzer cleared under K001250, K041726, K051187, and K082515, resulting in the ***modified*** REXEED-SX/LX Series Dialyzer. The information and data provided in this Special 510(k) Premarket Notification establish that the ***modified*** REXEED-SX/LX Series Dialyzer is substantially equivalent in intended use/indications for use, design, principle of operation, technology, materials, specifications, and performance to the predicate REXEED-SX/LX Series Dialyzer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 6, 2013

Asahi Kasei Medical Co., Ltd.
% Ms. Patsy J. Trisler, JD, RAC
Vice President, Regulatory & Clinical Affairs
Qserve Group B.V.
154 Main Street, Suite #2
CHARLESTOWN NH 03603

Re: K121409
Trade/Device Name: Asahi REXEED-SX/LX Series Dialyzer
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: December 20, 2012
Received: December 27, 2012

Dear Ms. Trisler:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K121409

Device Name: Asahi REXEED-SX/LX Series Dialyzer

Indications for Use:

A. REXEED-SX/LX Dialyzers is intended for use for hemodialysis treatment of patients who have chronic or acute renal failure.

B. REXEED SX/LX Dialyzers must be used in accordance with the instructions for a physician familiar with hemodialysis and familiar with the conditions of the patient.

C. REXEED SX/LX Dialyzers have been tested *in vitro* under single use conditions.

Prescription Use: ___X___ AND/OR Over-the-Counter Use: _____
(21 CFR § 801 Subpart D) (21 CFR §07 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
2013.02.06 15:06:01 -05'00'

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121409