DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 17, 2015

Asahi Kasei Medical Co., Ltd.
% Patsy Trisler
Regulatory Consultant
Qserve Group Us, Inc.
5600 Wisconsin Avenue, #509
Chevy Chase, Maryland 20815

Re: K153344
Trade/Device Name: Asahi REXEED-S Series Dialyzer
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI
Dated: November 17, 2015
Received: November 19, 2015

Dear Patsy 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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Herbert P. Lerner -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K153344

Device Name

Asahi REXEED-S Series Dialyzer

Indications for Use *(Describe)*

REXEED-S Series Dialyzer is intended for use in hemodialysis for the treatment of patients suffering from acute or chronic renal failure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

REXEED-S Series Dialyzer

SUBMITTER

Submitter Name and Address:	Contact:
Asahi Kasei Medical Co., Ltd. 1-105, Kanda Jinbocho, Chiyoda-ku, Tokyo 101-8101 Japan	Patsy J. Trisler, JD, RAC Regulatory Consultant Qserve Group US, Inc. Patsy.trisler@qservegroup.com 301.652.5344

Date Prepared: November 17, 2015

DEVICE:

Trade Name: Asahi REXEED-S Series Dialyzer

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

Classification Name, Class, Product Code and Panel

Classification Name and Regulation Number	Class	Product Code	Panel
High Permeability Hemodialysis Systems, 21 CFR 876.5860	II	KDI	Gastroenterology and Urology

PREDICATE DEVICE(S):

Asahi REXEED-S Series Dialyzer:

K001250, August 16, 2000;
K041726, July 23, 2004; and
K051187, June 8, 2005

DEVICE DESCRIPTION

The line of Asahi REXEED-S Series Dialyzer (hereafter referred to as REXEED-S) is a family of high permeability hollow fiber dialyzers intended for the treatment of patients with acute or chronic renal failure.

REXEED-S is designed for single use.

REXEED-S is constructed of hollow fiber membrane housed within a plastic housing of Styrene-Butadiene block copolymer and is subject to gamma-ray irradiation prior to shipment.

DESCRIPTION OF DEVICE MODIFICATIONS:

This Special 510(k) describes the following modifications to the referenced, previously-cleared Asahi dialyzers:

- Change in the material formulation ratio of housing (Styrene-Butadiene block copolymer)
- Change in the material formulation of Stoppers (blood and dialysate side):

  The material formulation change of stoppers from “Composite of Styrene-Ethylene-Butadiene-Styrene (SEBS) elastomer and Polyethylene” to “Polyethylene and Hydrogenated Styrene-Butadiene block copolymer ”.

INDICATIONS FOR USE

REXEED-S Series Dialyzer is intended for use in hemodialysis for the treatment of patients suffering from acute or chronic renal failure.

DESIGN CONTROLS: EVALUATION OF DEVICE MODICATIONS

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 verification tests based on the result of the risk analysis and design input were performed to verify those modifications. All test results met the acceptance criteria, and proved those modifications to be appropriate.

CONCLUSION OF SUBSTANTIAL EQUIVALENCE

Asahi made modifications as described above to the original REXEED-S Series Dialyzer cleared under K001250, K041726 and K051187. The information and data provided in this Special 510(k) Premarket Notification establish that the modified REXEED-S Series Dialyzer is substantially equivalent in the intended use/indications for use, design, principle of operation, technology, materials, specifications, and performance to the original referenced REXEED-S Series Dialyzer 510(k)s.