DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 3, 2017

Asahi Kasei Medical Co., Ltd.
% Megan Shackelford
Principal, Consulting Services
Boston Biomedical Associates, LLC
100 Crowley Drive, Suite 216
Marlborough, MA 01752

Re: K162248
Trade/Device Name: Asahi ViE-U Series Dialyzer
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI
Dated: April 3, 2017
Received: April 4, 2017

Dear Megan Shackelford:

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,

Joyce M. Whang -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)*
K162248

Device Name
Asahi ViE-U Series Dialyzer

Indications for Use *(Describe)*
ViE-U is intended for use in hemodialysis for the treatment of patients who have acute or chronic renal failure. ViE-U is intended for single use only.

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**

AsahiKASEI ASAHI KASEI MEDICAL CO., LTD.

(As Required By 21 CFR 807.92) Date Prepared: April 3, 2017

I. SUBMITTER

| Submitter Name and Address | Contact |
|---|---|
| Asahi Kasei Medical Co., Ltd.<br>1-105, Kanda Jinbocho,<br>Chiyoda-ku, Tokyo 101-8101<br>Japan | Megan M. Shackelford<br>Principal, Consulting Services<br>Boston Biomedical Associates<br>100 Crowley Drive Suite 216<br>Marlborough, MA 01752 |

II. DEVICE

| | |
|---|---|
| **Trade Name**: | Asahi ViE-U Series Dialyzer |
| **Common Name**: | Hemodialyzer, High Permeability<br>Hemodialysis System |
| **Classification** | 21 CFR 876.5860, Class II |
| **Product Code** | KDI |
| **Panel** | Gastroenterology and Urology |

III. PREDICATE DEVICES

| |
|---|
| Asahi APS Series Dialyzers:<br>K001250, August 16, 2000, and K041726, July 23, 2004 |
| CLIRANS E-Series Hollow Fiber Dialyzers (Terumo Corporation)<br>K003425, February 1, 2001, and K013550, November 20, 2001 |

IV DEVICE DESCRIPTION

The ViE-U is a high flux hollow fiber hemodialyzer. The device is sold sterile and is intended for single use only.

All the materials including the hollow fiber membrane, housing, headers, potting material and stoppers are identical to those previously cleared in the predicate device (APS). The additional coating of vitamin E on the hollow fiber membrane uses an equivalent material and technology to the predicate device (CLIRANS).

## V. INDICATIONS FOR USE

ViE-U is intended for use in hemodialysis for the treatment of patients who have acute or chronic renal failure. ViE-U is intended for single use only.

## VI COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed device (ViE-U) is substantially equivalent to the predicate device (APS) in terms of materials, principles of operation and device design. The proposed device was tested and compared with the predicate device (APS) for performance specifications. Additionally, the vitamin E coating of the proposed device uses an equivalent material and technology to that of the predicate device (CLIRANS). Considering these factors together, the proposed device was shown to be substantially equivalent to the predicate devices currently cleared through the 510(k) process.

## VII PERFORMANCE DATA

Asahi has performed testing in conformance with the special controls for High Permeability Hemodialysis System, 21 CFR 876.5860, and the FDA document "Guidance for the Content of Premarket Notifications for Conventional and High Permeability Hemodialyzers" including:

- Biocompatibility testing for external communicating devices, circulating blood, prolonged contact per ISO 10993-1;
- *In vitro* performance testing per ISO 8637 for
  - Clearance (urea, creatinine, phosphate, and vitamin $B_{12}$ at blood flow rates from 200 up to 500 mL/min.)
  - Pressure drop
  - $K_{UF}$
  - Priming volume (Blood compartment volume)
  - Maximum TMP
  - Structural integrity

- Sterilization validation per ISO 11137-2;
- Pyrogenicity testing;
- Expiration date testing;
- Packaging and transportation testing per ASTM D4169-14;
- Clinical performance including *in vivo* $K_{UF}$ and removal rates for urea, albumin, and beta 2-microglobulin.

The clinical study was a prospective, open-label, non-randomized, single-armed, controlled study at a single site in Canada per ISO 14155. Seventeen patients were enrolled in the study and received treatment sessions in three study phases. Each patient began the study by receiving treatments with their current standard of care (control dialyzer) for 6 initial sessions (two weeks), followed by treatments with the ViE-21U for 36 sessions (12 weeks), and concluded the study with 6 final treatments with the control dialyzer (two weeks). The clinical performance of the ultrafiltration coefficient ($K_{UF}$) and the removal rates for urea, creatinine, albumin and beta 2-microglobulin were evaluated for both the control and the ViE-21U dialyzers. In addition to performance data, biocompatibility and safety data were collected during the study, including: measurements of white blood cells, platelets and complement activation; type and number of adverse events; and type and number of device malfunctions. The clinical performance and biocompatibility were calculated based on the 12 patients who completed the 36 sessions with the ViE-21U dialyzer, while the safety evaluation was performed on all 17 enrolled patients. The clinical performance and biocompatibility evaluation showed equivalence of the ViE-21U and control dialyzers. Two adverse events determined to be possibly related (possible delayed hypersensitivity reaction) to the use of the ViE-21U occurred in one patient: pruritus and full body rash. These events were resolved with medication (diphenhydramine and prednisone) without sequelae, and the patient was transitioned back to the original hemodialyzer. There were no serious adverse events determined to be related to the use of the ViE-21U. The results of this clinical study show that the ViE-U was used effectively as a hemodialyzer in patients who have renal failure and was shown to be safe as compared to the control dialyzer.

## VIII CONCLUSION

All design verification tests and *in vivo* validation of clinical study demonstrated that ViE-U is substantially equivalent in intended use, design, principle of operation, technology, materials, specifications, and performance to APS cleared under K001250 and K041726 and CLIRANS cleared under K003425 and K013550.