DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 11, 2017

B. Braun Avitum AG
% Tracy Maddock
Sr. Regulatory Affairs Specialist
B. Braun Medical, Inc.
901 Marcon Boulevard
Allentown, PA 18109

Re: K170574
Trade/Device Name: Diacap Pro Dialyzer
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI
Dated: February 24, 2017
Received: February 27, 2017

Dear Tracy Maddock:

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)*

K170574

Device Name

Diacap Pro Dialyzer

Indications for Use *(Describe)*

The Diacap Pro Dialyzer is designed for single use in acute and chronic hemodialysis.

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.

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1. 510(k) SUMMARY K170574

APPLICANT: B. Braun Avitum AG
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DATE August 11, 2017

DEVICE NAME: Diacap Pro Dialyzer

Models: Diacap Pro 13H, Diacap Pro 16H,
Diacap Pro 19H

COMMON OR USUAL NAME: High Permeability polysulfone high flux dialyzer

DEVICE CLASSIFICATION: Class II per 21 CFR § 876.5860, Dialyzer, High Permeability With or Without Sealed Dialysate System
Product Code: KDI
Classification Panel: Gastroenterology/Urology

PREDICATE DEVICE: Diacap HI PS (10, 12, 15, 18, 20) Hemodialyzers, (K071518)

DESCRIPTION:

The Diacap Pro dialyzer is a polysulfone high flux dialyzer with the surface areas 1.3 sqm, 1.6 sqm, 1.9 sqm. It is designed for single use in acute and chronic hemodialysis. The dialyzer is gamma sterilized, with a non pyrogenic fluid path, and does not contain natural rubber latex.

INDICATIONS FOR USE:

The Diacap Pro Dialyzer is designed for single use in acute and chronic hemodialysis.

SUBSTANTIAL EQUIVALENCE:

The Diacap Pro dialyzer is substantially equivalent to the Diacap HIPS dialyzer (K071518).

Comparison of Technological Characteristics with the Predicate Device

The proposed device has the same indications for use (for single use in acute and chronic hemodialysis) and the same principle of operation as the predicate device. The proposed device is similar in design with respect to components and materials of construction. Both devices are provided as sterile, nonpyrogenic, individually packaged devices.

A table summarizing the comparison between the Diacap Pro Dialyzer and the predicate device is provided below.

	Proposed Device B. Braun Avitum AG Diacap Pro Dialyzer			**Predicate Device B. Braun Avitum AG Diacap HI PS Dialyzers (K071518)**			
Dialyzer model	13H	16H	19H	12	15	18	20
Indications for use	Designed for single use in acute and chronic hemodialysis			Designed for single use in acute and chronic hemodialysis			
Membrane Type	Asymmetric microporous hollow fiber			Asymmetric microporous hollow fiber			
Chemical composition of membrane	Polysulfone 90-99% by weight, Polyvinylpyrrolidone 1-10% by weight			Polysulfone 90-99% by weight, Polyvinylpyrrolidone 1-10% by weight			
Effective membrane surface area (m^2)	1.3	1.6	1.9	1.2	1.5	1.8	2.0
Number of fibers (mean)	8800	10840	12870	8180	10150	12250	13310
Mean effective (free) length of fibers (mm)	235			235			
Fiber inner diameter (nominal) in µm	200			200			
Wall thickness (nominal)	37 µm with 2 layers: separation layer: 1 µm thickness support layer: 36 µm thickness			40 µm with 2 layers: separation layer: 1 µm thickness support layer: 39 µm thickness			
Sterilization	Gamma			Gamma			
Volume, blood compartment (mL)	82	100	120	68	90	110	121
Outer diameter cylindrical part (mm)	39.6	42.6	47.6	39.6	42.6	47.6	47.6
Outer diameter (mm) blood cap	54.0	57.4	62.4	54.0	57.4	62.4	62.4
Length without protection cap (mm)	294.0	294.6	294.6	293	293	293	293
Connector blood side	Designed According to ISO 8637			Designed According to ISO 8637			
Connector dialysate fluid side	Designed According to ISO 8637			Designed According to ISO 8637			

The differences between the predicate device and the proposed device include:

- Alternative suppliers for PVP and PSU in addition to a new material supplier for potting and silicone rubber
- Color change of blood port caps and protective caps
- Change in design characteristics of the membrane including new packaging density (new surface areas), change in the wall thickness and change to the fiber microondulation.

The differences, between proposed device and predicate device, do not raise any new issues of safety and effectiveness

Performance Testing

The proposed Diacap Pro dialyzers were subjected to functional and performance testing to assess the effects of the modified characteristics and to demonstrate equivalence with the predicate devices.

The following in-vitro testing was performed on the proposed device in accordance with the methods listed in the FDA Guidance for the Content of Premarket Notifications for Conventional and High Permeability Hemodialyzers and in ISO 8637.

- ultrafiltration rate
- pressure drop blood side and dialysate side
- clearances of urea, creatinine and vitamin B12

The following comparative testing was performed on the proposed and predicate device:

- mechanical hemolysis

The following clinical testing was performed on the proposed device in accordance with the methods listed in the FDA Guidance for the Content of Premarket Notifications for Conventional and High Permeability Hemodialyzers:

- in-vivo ultrafiltration coefficient

Results of the testing demonstrate that the proposed device performs similarly to the predicate device and can be used safely and effectively according to its intended use.

CONCLUSION:

Results of functional and performance testing conducted on the proposed device demonstrate that the Diacap Pro dialyzers are substantially equivalent to the predicate device.