DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 9, 2015

DEKA Research and Development Corp.
Roger A. Leroux
Director of Regulatory and Clinical
340 Commercial Street
Manchester, NH 03101

Re: K151525
Trade/Device Name: Amia Automated PD System with Sharesource
Regulation Number: 21 CFR§ 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: FKX
Dated: August 9, 2015
Received: September 10, 2015

Dear Roger A. Leroux,

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,

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

4. INDICATIONS FOR USE

510(k) Number (if known):_K151525_____

Device Name: Amia Automated PD System with Sharesource

Amia Automated PD System:

The Amia Automated PD System is intended for automatic control of dialysate solution exchanges in the treatment of adult renal failure patients undergoing peritoneal dialysis.

All therapies using the Amia Automated PD System must be prescribed and performed under the responsibility of a physician who is familiar and well informed about peritoneal dialysis.

Sharesource:

The Sharesource portal is intended for use by healthcare professionals to remotely communicate new or modified treatment parameters with compatible dialysis instruments and transfer completed treatment data to a central database to aid in the review, analysis, and evaluation of patients' historical treatment results. This system is not intended to be a substitute for good clinical management practices, nor does its operation create decisions or treatment pathways.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use_____ (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

5. 510(K) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR 807.92.

Submitter's Information

510(k) Sponsor: DEKA Research & Development
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Manchester, NH 03101

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Device Information

Common/Usual Name:	Automated peritoneal dialysis (APD) cycler
Trade/Proprietary Name:	Amia Automated PD System with Sharesource
Classification Name:	Peritoneal dialysis system and accessories (21 CFR 876.5630)
Device Classification:	II
Product Code:	FKX
Device Panel:	Gastroenterology/Urology

Predicate Device(s)

The Amia Automated PD System is substantially equivalent to the Amia Automated PD System, which was previously cleared under application K124018. The HomeChoice PRO Automated Personal Cycler previously cleared under K102936 is also included as a reference predicate. The Sharesource software is substantially equivalent to Baxter Healthcare Corporation's RenalSoft v.2.0, which was previously cleared under K061515. The PDK accessory for the Amia Automated PD System (K124018) is also included as a reference predicate.

Device Description

The Amia Automated PD System with Sharesource (hereafter "Amia/Sharesource System") device is intended for automatic control of dialysate solution exchanges in the treatment of adult renal failure patients undergoing peritoneal dialysis therapy. The system automatically cycles peritoneal dialysis fluid in the amounts and at the times prescribed by a clinician familiar and well informed about peritoneal dialysis. The clinician may use the optional Sharesource software

accessory to remotely communicate with the Amia Automated PD System. Sharesource will allow the transfer of treatment data originating from the treatment device to the clinician for review of patient historical treatment results. It will also allow the clinician to adjust the device settings of the Amia Automated PD System remotely. Changes to device program by the physician require the patient to review and accept the changes prior to the change of the device program on the cycler. If the patient does not accept the changes, the device will not accept the modified program. The Amia Automated PD System with Sharesource does not include any real-time remote monitoring or real-time remote programming capabilities. A device description is included in Section 11 of this submission.

Indications for Use

Amia Automated PD System:

The Amia Automated PD System is intended for automatic control of dialysate solution exchanges in the treatment of adult renal failure patients undergoing peritoneal dialysis.

All therapies using the Amia Automated PD System must be prescribed and performed under the responsibility of a physician who is familiar and well informed about peritoneal dialysis.

Sharesource:

The Sharesource portal is intended for use by healthcare professionals to remotely communicate new or modified treatment parameters with compatible dialysis instruments and transfer completed treatment data to a central database to aid in the review, analysis, and evaluation of patients' historical treatment results. This system is not intended to be a substitute for good clinical management practices, nor does its operation create decisions or treatment pathways.

Technological Characteristics

The Amia/Sharesource System has similar technological characteristics as compared to the predicate device(s). Risk analysis has been completed and potential hazards associated with the modifications have been identified and mitigated. All potential risks were deemed acceptable after mitigation.

Performance Data

The device was tested to verify conformance with the design specifications and applicable industry standards and to verify compatibility and functionality with Sharesource. Complete system verification testing was performed to ensure that the device functions as intended and met all requirements.

In addition, Human Factors evaluations for the Amia Automated PD System and the Sharesource software were conducted in simulated environments to ensure user needs and intended uses were met.

Conclusion

Based on demonstrable evidence, the device modifications described within this submission do not affect the intended use, the fundamental technology or operating principles of the device, nor do any material changes raise safety or effectiveness issues with regard to the Amia Automated PD System with Sharesource. DEKA finds the Amia Automated PD System with Sharesource to be substantially equivalent to the predicate device(s).