JUN 1 4 2013

## 4. 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
340 Commercial Street
Manchester, NH 03101

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Director, Regulatory and Clinical Affairs
DEKA Research & Development Corporation
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### Device Information

| | |
|---|---|
| Common/Usual Name: | Automated peritoneal dialysis (APD) cycler |
| Trade/Proprietary Name: | Amia Automated PD System<br>*(formerly the Voyager Peritoneal Dialysis System)* |
| Classification Name: | Peritoneal dialysis system and accessories (21 CFR 876.5630) |
| Device Classification: | II |
| Product Code: | FKX |
| Device Panel: | Gastroenterology/Urology |

### Predicate Device

The Amia Automated PD System is substantially equivalent to the Voyager Peritoneal Dialysis System, which was previously cleared under application K103220.

### Device Description

The Amia Automated PD System is used for automatic control of dialysate solution exchanges in the treatment of adult renal failure patients undergoing peritoneal dialysis therapy. The Amia device automatically cycles peritoneal dialysis fluid in the amounts and time prescribed by a clinician.

### Indications for Use

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.

**Technological Characteristics**

The Amia device has the same technological characteristics as compared to its predicate device. 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 Amia device has been evaluated for substantial equivalence to its predicate device.

It is in conformance with the design specifications and applicable industry standards for software development. It was further verified for system compatibility with the devices with which it communicates. Complete system validation and software regression testing was performed to ensure that the device functions as intended and met all software requirements.

Standards testing included:

- Software validation and regression testing
- Biocompatibility testing to ISO 10993-1; -4, -5, -7, 10, -11 and -12
- Sterilization Testing
- Ethylene Oxide Sterilization Residual testing to ISO 10993-7
- Electromagnetic compatibility (EMC) testing to IEC 60601-1-2
- Electrical safety testing to IEC 60601-1
- General requirements for safety, Programmable electrical medical system–IEC 60601-1-4
- Medical electrical equipment – General requirements for safety – Collateral Standard: Usability
- Degrees of Protection Provided by Enclosures – IEC 60529
- Standard Practice for Assessment of Hemolytic Properties of Materials – ASTM F756-08
- Standard Practice for Performance Testing of Shipping Containers and Systems – ASTM D4169

- Packaged-Products 150 lb (68 kg) or Less Basic Requirements – ISTA 2A
- Pyrogen test (USP Rabbit Test) – USP 32 .

Standards testing results demonstrated that all applicable sections of the identified standards were in conformance to pre-determined acceptance criteria.

Performance testing – All performance requirements were tested under simulated and actual environmental conditions using worst case scenarios to confirm compliance to the stated requirements.

**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; therefore, DEKA finds it to be substantially equivalent to the predicate device.

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

June 14, 2013

DEKA Research & Development Corp.
% Mr. Roger Leroux
Director of Regulatory and Clinical Affairs
340 Commercial Street
MANCHESTER NH 03101

Re: K124018
Trade/Device Name: Amia Automated PD System
Regulation Number: 21 CFR§ 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: FKX
Dated: May 23, 2013
Received: May 30, 2013

Dear Mr. 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,

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

## 3. INDICATIONS FOR USE

**510(k) Number (if known):** K124018

**Device Name: Amia Automated PD System**

Indications for Use:

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.

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

Herbert P. Lerner -S

K124018