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

September 10, 2014

Home Dialysis Plus
Nancy Gallo
Senior Vice President, Regulatory Affairs
257 Humboldt Court
Sunnyvale, CA 94089

Re: K140841
Trade/Device Name: Tablo™ Cartridge
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FJK
Dated: August 8, 2014
Received: August 11, 2014

Dear Nancy Gallo,

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

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 on last page.

510(k) Number *(if known)*
K140841

Device Name
Tablo™ Cartridge

Indications for Use *(Describe)*
The Tablo™ Cartridge is a single use, disposable arterial and venous bloodline set intended to provide extracorporeal access during hemodialysis. The Tablo™ Cartridge is compatible only with the Tablo™ Hemodialysis System.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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5. 510(k) Summary

This 510(k) Summary is 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 Part 807.92.

5.1 Submitter's Information

Submitter's Name: Company: Address:	Moshe Pinto, CEO HDPlus 257 Humboldt Ct, Sunnyvale, CA 94089
Contact Person:	Nancy Gallo, Senior Vice-President, Regulatory Affairs
Phone:	510.682.6505
Facsimile:	408.329.9091
Email:	ngallo@homedialysisplus.com
Date of Summary Preparation:	March 31, 2014

5.2 Device Information

Trade Name:	Tablo™ Cartridge
Common Name:	Blood Tubing Set
Classification Name:	Hemodialysis system and accessories
Classification Number:	Class II per 21 CFR 876.5820
Product Code:	FJK (Set, Tubing, Blood, With And Without Anti-Regurgitation Valve)
Classification Panel:	Gastroenterology/Urology

5.3 Predicate Device Information

Fresenius Blood Tubing Set (K120823)

5.4 Device Description

The Tablo™ Cartridge comprises a single-use, sterile Blood Tubing Set attached to an Organizer. The Organizer ensures proper placement of the Blood Tubing Set with the Tablo Hemodialysis System. The Blood Tubing Set consists of an arterial line, a venous line, an adaptor to connect the two lines, a saline line, a pressure transducer protector, a venous drip chamber, an arterial pressure pod, and a heparin syringe line. The Tablo Cartridge is developed exclusively for use with the Tablo Hemodialysis System. It is single-use, offered in one configuration, and provided sterile.

5.5 Indications for Use

The Tablo Cartridge is a single use, disposable arterial and venous bloodline set intended to provide extracorporeal access during hemodialysis. The Tablo Cartridge is compatible only with the Tablo Hemodialysis System.

5.6 Technological Characteristics

The Tablo Cartridge (Subject Device) utilizes Fresenius Blood Tubing Set (K120823) as its Predicate.

5.6.1 Tablo Cartridge vs. Fresenius Blood Tubing Set (K120823):

The Subject and Predicate Devices have equivalent technological characteristics:

- Intended Use – To provide extracorporeal access during hemodialysis.
- Materials – Primary fluid path materials are Polyvinyl Chloride (PVC) and Polypropylene (PP).
- Design & Construction - Polyvinyl Chloride (PVC) tubing of various lengths and diameters, with color-coded pinch clamps, color-coded injection ports, heparin line, saline line, and pressure monitoring components.
- Sterility - Sterile, single use, non-pyrogenic.
- Priming Volume - Priming Volume of ≤ 300 ml

Minor differences exist in the technological characteristics of the Subject and Predicate Devices. None of the minor differences raise any new or different questions of safety or effectiveness. The differences include:

- Subject Device is mounted on an organizer to facilitate interface with the machine's front panel. The Predicate does not have an organizer and the tubing is uncoiled and attached to the machine.
- The Inner Diameter (ID) of the Blood Pump Segment of Subject Device is smaller than that of the Predicate Device.
- The default configuration of the access point used for both systems is a double needle configuration, though the Predicate is also equipped with the option of a single needle configuration.
- The pressure measuring component of the Tablo Cartridge is different from that of the Predicate.

5.7 Performance Data

The following Performance Testing, developed in accordance with appropriate guidance documents and relevant standards, has been performed on the Subject Device to support the determination of substantial equivalence:

- Functional testing.
- Biocompatibility testing.
- Packaging and shelf life testing.
- Sterilization validation.
- Pyrogenicity testing for the blood fluid path.

The results of all these tests demonstrated the Tablo Cartridge is safe and does not raise new or different questions of safety or effectiveness as compared to the Predicate.

5.8 Conclusion

The Performance Testing demonstrated the Tablo Cartridge meets all performance specifications and complies with applicable standards and FDA Guidance Documents. The Tablo Cartridge is substantially equivalent to the Predicate, and the minor differences in the technological characteristics of the Subject and the Predicate Devices do not raise any new or different questions of safety or effectiveness.