May 4, 2021

IPAX, Inc
Jeff Baldwin
CEO
2700 S Raritan St
Englewood, Colorado 80110

Re: K200893
Trade/Device Name: ProntoPump Sterile Tube Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI, NEP
Dated: April 2, 2021
Received: April 5, 2021

Dear Jeff Baldwin:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Payal Patel
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200893

Device Name
Pronto Pump Sterile Tube Set

Indications for Use *(Describe)*
The Pronto Pump Tube Set is a part of the Pronto Pump System. This tube set provides peristaltic pump driven fluid transfer that facilities repeatable drug dosage distribution and reconstitution in healthcare environments. The Pronto Pump Tube set provides the fluid path way and pumping mechanism for the pump system.

The device is for use with IV bags, syringes, elastomeric infusers, and other drug administration containers. Sets are sold sterile.

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.

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510(K) Summary K200893

Submitted by:	IPAX, INC. 2700 S Raritan St Englewood, CO 80110 Registration Number: 1720734
Preparation date:	April 23, 2021
Contact person:	Jeff Baldwin, CEO
Telephone number:	303-975-2444 x 630
Fax number:	N/A
E-mail Address:	jeffb@ipaxinc.com
Manufacturing Site Address:	IPAX, INC. 2700 S Raritan St Englewood, CO 80110
Device Trade or Proprietary Name:	ProntoPump Sterile Tube Set
Common Name:	Set, I.V. Fluid Transfer
Product code:	LHI
Secondary Product Code:	NEP System/Device, Pharmacy Compounding
Regulatory Class:	Class II
Regulation number:	21 CFR 880.5440 Intravascular administration set
Classification Panel:	General Hospital
Model number:	3003852 Sterile Tube Set, Universal Spike – Luer Lock 3003854 Sterile Tube Set, Luer Lock to Luer Lock

Predicate Device:	K062909 Repeater Pump II Tube Sets
Common Name :	Set, I.V. Fluid Transfer
Regulation Number:	21 CFR § 880.5440 Intravascular administration set,
Product Code:	LHI

Device Description:
The ProntoPump sterile tube set is a single channel tube set for use with the ProntoPump pharmacy pump. It consists of clear plastic tubing connected to a silicone tube that functions as a peristaltic pumping chamber. Peristaltic pumps function by a roller compressing the pump tubing and rolling along the length of the tube, squeezing the fluid inside the tube from one end to the other. It has a plastic cassette that holds the pumping chamber in place for insertion into the ProntoPump, which provides the rollers that the force the fluid to move. The proximal and distal ends of the PVC tubing have connectors for various devices and containers. Using the ProntoPump, the tube set is used to deliver specified volumes of liquid into a final dosing container in hospital pharmacies or compounding pharmacies. The device is for use with IV bags, syringes, elastomeric infusers, and other drug administration containers. Sets are sold sterile.

The cassette is non-fluid-contact and helps hold the tubing in place for loading. It has a machine-readable barcode that can be read by the pharmacy pump. The barcode includes information about the particular tube set item number, lot number, and expiration date, which is used by pharmacy pump to facilitate set up of the tubing.

The tube set is intended to be used by trained healthcare personnel, and is not intended to be used for direct patient contact. Tube sets are packaged individually in a peel pouch and sterilized by radiation.

Indications for Use
The ProntoPump Sterile Tube Sets are fluid transfer tube sets used in conjunction with the ProntoPump pharmacy pump in hospital and compounding pharmacies to provide a pathway through which fluid is transferred from one source container into another suitable container.

The device is for use with IV bags, syringes, elastomeric infusers, and other drug administration containers. Sets are sold sterile.

Comparison of Technological Characteristics with The Predicate Device
The ProntoPump sterile tube set has the same indications for use (to provide a fluid path for the dispensing of fluids using a pharmacy pump), and substantially the same tubing and connections (PVC tubing, ABS spike, ABS fittings) as the predicate device. The tube set uses a silicone tubing to provide peristaltic pump driven fluid transfer, while the predicate device used a high speed syringe pump

to provide fluid transfer. Both devices are provided as sterile, nonpyrogenic, individually packaged devices to be used with their respective pharmacy pumps.

Comparison of Technological Characteristics with the Predicate

Feature	ProntoPump Sterile Tube Set (K200893)	Repeater Pump II Tube Set (K062909)	Discussion/ Justification
Indications for use	The ProntoPump Sterile Tube Sets are fluid transfer tube sets used in conjunction with the ProntoPump pharmacy pump in hospital and compounding pharmacies to provide a pathway through which fluid is transferred from one source container into another suitable container. The device is for use with IV bags, syringes, elastomeric infusers, and other drug administration containers. Sets are sold sterile.	The Repeater Pump II tube sets are fluid transfer tube sets used in conjunction with the Repeater Pump II pharmacy pump in hospital and compounding pharmacies to provide a pathway through which fluid is transferred from one source container into another suitable container.	Same
Intended Use	The ProntoPump Sterile Tube Sets are fluid transfer tube sets used in conjunction with the ProntoPump pharmacy pump in hospital and compounding pharmacies to provide a pathway through which fluid is transferred from one source container into	The Repeater Pump II tube sets are fluid transfer tube sets used in conjunction with the ProntoPump pharmacy pump in hospital and compounding pharmacies to provide a pathway through which fluid is transferred from one source container into another suitable	Same

Feature	ProntoPump Sterile Tube Set (K200893)	Repeater Pump II Tube Set (K062909)	Discussion/ Justification
	another suitable container.	container.	
Usage	Single use. Rx Only	Single Use. Rx Only	Same
Target Population	Customers for the tube sets are ProntoPump pharmacy pump users, including hospital and home care pharmacist and pharmacy technicians. These tube sets are used by trained personnel, and do not have direct contact with any patient.	Customers for the tube sets are Baxa Repeater Pump 2™ pump users, including hospital and home care pharmacist and pharmacy technicians. These tube sets are used by trained personnel, and do not have direct contact with any patient.	Same
Anatomical	Not intended for patient contact	Not intended for patient contact	Same
Where Used	This product is used by Pharmacists and Pharmacy technicians both inside and outside of flow hoods	This product is used by Pharmacists and Pharmacy technicians both inside and outside of flow hoods	Same
Connections	Luer fittings, spikes for IV bags, and other standard IV, or oral/ topical connections. Different sets will have different connections depending on the source and final containers.	Luer fittings, spikes for IV bags, and other standard IV, or oral/ topical connections. Different sets will have different connections depending on the source and final containers.	Same

Feature	ProntoPump Sterile Tube Set (K200893)	Repeater Pump II Tube Set (K062909)	Discussion/ Justification
Biocompatibility	ISO 10993-1, Externally Communicating, Indirect	ISO 10993-1, Externally Communicating, Indirect	Same
Inlet and Outlet Materials	Polyvinyl Chloride (PVC): tubing with no Di (2-ethylhexyl) phthalate (DEHP) added.	PVC tubing with no DEHP added.	Same
Pumping Mechanism	Uses a silicone tube to provide peristaltic pumping.	Uses a custom molded syringe as a pumping chamber.	Both methods achieve the intended use of transferring fluid from a source container into another container safely and effectively.
Pumping Chamber Material	Medical grade platinum cured Silicone tubing	Clear plastic cylinder containing a maximum of 10 mL, non-latex rubber piston, and a non-latex rubber valve to control direction of flow.	Different: The predicate device uses a high-speed syringe pump to transfer fluids from a source container into another suitable container. The ProntoPump uses a silicone tube to provide a peristaltic pumping action to transfer into another suitable container. The methods of transfer are substantially equivalent in terms of safety and effectiveness of achieving the intended use
Spike Material	Acrylonitrile Butadiene Styrene (ABS)	ABS	Same
Luer Connector Materials	ABS	ABS	Same
Sterilization	Sterilized by Gamma radiation (10 ^ -6)	Sterilized by Gamma radiation (10 ^ -6)	

Feature	ProntoPump Sterile Tube Set (K200893)	Repeater Pump II Tube Set (K062909)	Discussion/ Justification
Tube set maximum usage	Labelled for 40 L maximum use	Labelled for 200 L maximum use	Different Sterile sets in critical care pharmacies are only used for 24 hours, and most doses are below 250 mL, the 24 hour limit is identified in the ProntoPump Sterile Tube Set Instructions for Use. The 40L limit will meet the needs of almost all users. The 40L limit is identified in the ProntoPump device [510(k) exempt] instructions for use
Minimum Flow Rate at Top Speed	At least 21 mL /s at top speed	At least 11 mL /s	Different Most doses in critical care pharmacies are below 250 mL, and the higher flow rate of the predicate device does not provide significant value to the user. The flow rate of filling the dose container has no known impact on the safety or efficacy of the dose to the patient.

Feature	ProntoPump Sterile Tube Set (K200893)	Repeater Pump II Tube Set (K062909)	Discussion/ Justification
Volume Accuracy	+/- 5% from 1.0 mL to 5.0 mL +/- 4% above 5 mL	labelled as +/1 0.02 mL from 0.2 ml to 2.0 mL +/- 1% above 2.0 mL	Different The predicate device used a fixed sized, high speed syringe pump to achieve the stated accuracy of the volume transferred from source container to the final container. The ProntoPump tube sets use the silicone tubing in conjunction with the ProntoPump pharmacy pump to achieve the stated accuracy of the volume transferred from source container to the final container. Although the accuracy of the ProntoPump tube sets is not as precise as the predicate device, in the context of doses prepared in Hospital and Compounding Pharmacies the accuracy of the volume delivered to the final container have substantially equivalent safety and effectiveness.

Differences Compared to Predicate Device / Substantial Equivalence Discussion

The devices are similar in intended use, function, sterility, and packaging. The most notable physical difference is the predicate device uses a custom molded syringe as a pumping chamber. The ProntoPump sterile tube set uses a silicone tube to provide peristaltic pumping. Both methods achieve the intended use safely and effectively.

While the predicate device is labelled for deliveries as small as 0.2 mL, it is not for use on syringes smaller than 3mL. The ProntoPump sterile tube set is labelled for use down to 1.0 mL. This is since for practical reasons that is the smallest delivery users would be likely to put into a 3 mL syringe.

The volume accuracy claim of the predicate device was +/- 0.02 mL from 0.2 mL to 2.0 mL, and +/- 1% above 2.0 mL. The ProntoPump Tube Set provides accuracy of +/- 5% from 1.0 mL to 5.0 mL and +/- 4% above 5 mL. Although the accuracy of the ProntoPump tube sets is not as precise as the predicate device, in the context of doses prepared in Hospital and Compounding Pharmacies the accuracy of the volume delivered to the final container is substantially equivalent in terms of safety and effectiveness.

The technological and performance differences between the devices have been analyzed and it has been concluded no new issues of safety and effectiveness are presented in the new device compared to the predicate device. The results of the bench testing conducted demonstrate the subject device is substantially equivalent to the predicate device in the intended use, indications for use and functionality.

Summary of Performance Testing

Bench Testing

- ISO 8536-4:2019, Infusion equipment for-medical use- Part 4: Infusion sets for single use, gravity feed.
- ASTM D4169-16:2016 – Standard Practice for Performance Testing of Shipping Containers and Systems
- ISO 80369-7:2016 - Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

Biocompatibility

- ISO 10993-1:2018 - Biological evaluation of medical
- devices — Part 1: Evaluation and testing within a risk management process

- USP 788, Particulate Matter in Injections

Sterilization and Packaging

- ISO 11607-1:2019 - Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2019 - Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
- ISO 11137-1:2006 - Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 11137-2:2013 - Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose

Clinical or Animal Testing

N/A – No animal or clinical testing.

Substantial Equivalence Conclusion:

Based on the indication for use, the technological and performance characteristics, and results of performance testing, the subject device Pronto Pump Sterile tube sets have been demonstrated to be substantially equivalent to the legally marketed predicate device, K062909.