January 18, 2019

Kurin, Inc
℅ Neal Hartman
Independent Consultant
892 Summer Moon Road
San Marcos, California 92078

Re: K181895
Trade/Device Name: Kurin PIV18 Blood Culture Collection Set with Kurin Lock Technology, includes detachable, pressure-rated, 6" (152mm) microbore extension set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA, JKA
Dated: December 14, 2018
Received: December 17, 2018

Dear Neal Hartman:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181895

Device Name
Kurin PIV18 Blood Culture Collection Set with Kurin Lock Technology, includes detachable, pressure-rated, 6" (152mm) microbore extension set

Indications for Use *(Describe)*
Intended to connect to short peripheral catheter to obtain initial blood draw and when disconnected from the blood collection portion of the device, the pressure-rated extension set is intended to be utilized with infusions systems to administer IV fluids, medications, blood and blood products to the patient's vascular system and may be safety used with power injectors at pressures up to 325 psi.

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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K181895 – 510(K) SUMMARY

Submitter Information

Company Name:	Kurin, Inc.
Company Address:	10840 Thornmint Road Suite 111 San Diego, CA 92127
Company Phone:	(760) 612-6090
Contact Person:	Bob Rogers Chairman and CEO bobrogers@kurin.com
Date:	January 17, 2019

Device Identification

Device Trade Name:	Kurin PIV18 Blood Culture Collection Set with Kurin Lock Technology, includes detachable, pressure-rated, 6” (152mm) microbore extension set
Common Name:	Intravascular Administration Set/ Blood Collection Set
Product Models:	M-PIV18 - Kurin PIV18 Blood Culture Collection Set with Kurin Lock Technology, includes detachable, pressure-rated, 6” (152mm) microbore extension set (with Biomerieux Shield Blood Collection Holder) D-PIV18 – Kurin PIV18 Blood Culture Collection Set with Kurin Lock Technology, includes detachable, pressure-rated, 6” (152mm) microbore extension set (with BD Vacutainer Blood Collection Holder) T-PIV18 - Kurin PIV18 Blood Culture Collection Set with Kurin Lock Technology, includes detachable, pressure-rated, 6” (152mm) microbore extension set (with Short Saf-T Blood Collection Holder)
Classification Name(s):	Intravascular Administration Set
Classification Regulation(s):	880-5440
Device Class:	Class II
Product Code(s):	FPA, JKA
Advisory Panel:	General Hospital

Identification of Predicate Device

Predicate Identifier	Device Name	Regulation No.	Product Code	510(K) Number	Clearance Date
Primary	Nexus Pressure Rated Extension Sets	880.5440 Intravascular Administration Set	FPA	K092382	April 26, 2010
Secondary	Kurin Blood Culture Collection Set	862.1675 Tubes, Vials, Systems, Serum Separators, Blood Collection	JKA	K162233	December 23, 2016

Device Description

The Subject device is a sterile, single-use device that consist of a pressure-rated extension set and the blood culture collection set. The blood culture collection set incorporates a luer connection, flexible tubing, blood lock mechanism, and blood collection holder. The pressure-rated extension set is connected to the blood collection set via the luer connection. The Subject device is provided to the healthcare facility in this configuration.

The Peripheral IV (PIV) catheter is connected to the pressure-rated extension set via luer connection. Blood travels through the lumen of the Subject device into the blood lock mechanism where the initial draw of blood (approximately 1ml) is diverted and sequestered. The purpose of the sequestration is to automate the discard volume method (DVM). Once the sequestered volume is diverted and retained, the blood continues travel to the blood collection holder where the blood culture sample is obtained.

Once the blood draw process is completed, the blood collection set of the Subject device is disconnected from the pressure-rated extension set and discarded. The pressure-rated extension set is utilized as an infusion system to administer IV fluids, medications, blood and blood products to the patient's vascular system. The pressure-rated extension set is rated to 325 PSI.

Various blood collection holders are incorporated with the Subject device to interfaces with marketed blood culture bottles and vails. These blood collection holders are cleared under K912563 (Biomerieux Shield), K950432 (BD Vacutainer), and K081229 (Short Saf-T Holder). The blood collection holder incorporates a needle that is covered by elastomer boot. The culture bottle is inserted into the blood collection holder where the needle punctures the elastomer cap and provides a pathway for the blood to traveling into the culture bottle. The vacuum of the culture bottle pulls the blood. Once completed, the culture bottle is removed and the elastomer boot covers the needle and seals to fluid path.

Indications for Use

Intended to connect to short peripheral catheter to obtain initial blood draw and when disconnected from the blood culture collection set, the pressure-rated extension set is intended to be utilized with infusions systems to administer IV fluids, medications, blood and blood products to the patient's vascular system and may be safety used with power injectors at pressures up to 325 psi.

Comparison of Technological Characteristics with Primary Predicate Device

Comparison Feature	Subject Device	Primary Predicate Device (K092382)
Device Name	Kurin PIV18 Blood Culture Collection Set with Kurin Lock Technology, includes detachable, pressure-rated, 6" (152mm) microbore extension set	Nexus Pressure Rated Extension Set

Comparison Feature	Subject Device	Primary Predicate Device (K092382)
Regulation No.	880.5540 Intravascular Administration Set	880.5540 Intravascular Administration Set
Product Code	FPA	FPA
Indications for Use	Intended to connect to short peripheral catheter to obtain initial blood draw and when disconnected from the blood culture collection set, the pressure-rated extension set is intended to be utilized with infusions systems to administer IV fluids, mediations, blood and blood products to the patient's vascular system and may be safety used with power injectors at pressures up to 325 psi.	The Nexus Pressure Rated Extension Sets are intended for the use in today's growing professional healthcare environment, including healthcare facilities that utilize infusion systems to administer IV fluids, mediations, blood and blood products to the patient's vascular system and may be safety used with power injectors at pressures up to 325 psi.
Infusion Use?	Yes, Extension Set Only	Yes
Includes Blood Collection Capabilities	Yes	No
Shelf-Life	2 Years	5 Years
Pressure Rating, Extension Set	325 PSI	325 PSI
Maximum Flow Rate, Extension Set	10 mL/second	10 mL/second
Priming Volume, Extension Set	0.25 mL	0.25 mL
Single-Use?	Yes	Yes
Prescription Use?	Yes	Yes
Sterile?	Yes, EO	Yes, EO

The Pressure-Rated Extension Set on the Subject device is actually the predicate device thus the materials, constructions, and manufacturing processes are identical. Based on this, the Subject device is substantial equivalent to the predicated device from the fluid administration standpoint. In addition, the Subject device provides the ability for conduct initial blood draw prior to fluid administration.

The differences in the indication for use statement between the Subject device and the predicate device are not critical and does not affect the safety and effectiveness of the device. The indication for the Pressure-Rated Extension Set is the same however the Subject device is specific to the connection to a short peripheral catheter and its use in blood draws. The predicate device is connected to such devices and can be used in blood draws.

The blood collection technology was cleared under 510(k) K162233 (Secondary Predicate). Refer to the following table for a comparison with the Subject Device:

Comparison Feature	Subject Device	Secondary Predicate Device (K162233)
Device Name	Kurin PIV18 Blood Culture Collection Set with Kurin Lock Technology, includes detachable, pressure-rated, 6" (152mm) microbore extension set	Kurin Blood Culture Collection Set
Regulation No.	880.5540 Intravascular Administration Set	862.1675

Comparison Feature	Subject Device	Secondary Predicate Device (K162233)
		Tubes, Vials, Systems, Serum Separators, Blood Collection
Product Code	FPA, JKA	JKA
Indications for Use	Intended to connect to short peripheral catheter to obtain initial blood draw and when disconnected from the blood culture collection set, the pressure-rated extension set is intended to be utilized with infusions systems to administer IV fluids, mediations, blood and blood products to the patient's vascular system and may be safety used with power injectors at pressures up to 325 psi.	The Kurin Blood Culture Collection Set is a winged blood collection needle with flexible tubing intended for venipuncture to obtain blood samples. It is provided with a safety shield for covering the used venipuncture needle prior to disposal to aid in prevention of needlestick injury if manually activated after blood draw. For blood collection, the set also includes a safety shield and apparatus for connection to vacuum based collection vials
Infusion Use?	Yes, Extension Set Only	No
Blood Collection Capabilities	Yes, the Kurin blood lock mechanism sequesters the initial sample of blood and the blood collection holder is used to interface with a vacuum tube or culture bottle. There is no energy source, the device fills with blood by differences in pressure gradient.	Yes, the winged needle is used to access the patient's blood stream, the safety shield is used cover the needle after collection, the blood lock mechanism sequesters the initial sample of blood and the blood collection holder is used to interface with a vacuum tube or culture bottle. There is no energy source, the device fills with blood by differences in pressure gradient.
Venipuncture needle	No, luer connector	Yes
Pressure Rating, Extension Set	325 PSI	N/A
Maximum Flow Rate, Extension Set	10 mL/second	N/A
Priming Volume, Extension Set	0.25 mL	N/A
Single-Use?	Yes	Yes
Prescription Use?	Yes	Yes
Sterile?	Yes, EO	Yes, EO
Shelf-Life	2 Years	2 Years

The main differences between the Subject Device and the Secondary Predicate is the Secondary Predicate includes a venipuncture needle and it is strictly used for blood collection. The Subject Device does not include a venipuncture needle, includes a pressure-rated extension set, and is intended to be used with peripheral catheters for blood collection and the extension set is intended to be used with infusion systems. The Subject Device and Secondary predicate are made of the same materials.

Summary of Non-Clinical Tests Performed

- Sterilization
    - Sterilization Product Adoptions
    - Sterilization Cycle Comparison
- Shelf-Life (Accelerated Aging)
        - Packaging Integrity

        - Visual Inspection
        - Gross Leak (Bubble Emission)
        - Peel Seal Strength
    - Performance/Functionality
        - Blood collection portion of Subject device
- Performance/Functionality for pressure-rated extension set
    - Tensile Strength
    - Burst Pressure

Conclusion

The Subject device has demonstrated through performance testing that it is substantially equivalent to the commercially available predicate.