February 4, 2020

Kurin, Inc
Neal Hartman
VP, Regulatory Affairs/Quality Assurance
10840 Thornmint Road, Suite 111
San Diego, California 92127

Re: K191832
Trade/Device Name: Kurin Blood Culture Collection Set with Kurin Lock Technology, Push-Button Needle (Product models M-21221, M-21223, D-21221, D-21223, T-21221, T-21223)
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: January 3, 2020
Received: January 6, 2020

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/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 Geeta Pamidimukkala
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191832

Device Name
Kurin Blood Culture Collection Set with Kurin Lock Technology, Push-Button Needle
(Product models M-21221, M-21223, D-21221, D-21223, T-21221, T-21223)

Indications for Use *(Describe)*
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 the prevention of needle stick injury if manually activated after the blood draw. For blood collection, the set also includes a blood collection holder for connection to vacuum-based collection vials.

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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510(K) SUMMARY – K191832

Submitter Information

Company Name:	Kurin, Inc.
Company Address:	10840 Thornmint Road Suite 111 San Diego, CA 92127
Company Phone:	(888) 963-9056
Contact Person:	Bob Rogers Chairman and CEO bobrogers@kurin.com
Date:	February 3, 2020

Device Identification

Device Trade Name:	Kurin Blood Culture Collection Set with Kurin Lock Technology, Push-Button Needle
Common Name:	Blood Collection Set
Product Models:	M-21221 - Kurin Blood Culture Collection Set with Kurin Lock Technology, 21Ga Push Button Needle, Compatible with BioMerieux Bottles M-21223 - Kurin Blood Culture Collection Set with Kurin Lock Technology, 23Ga Push Button Needle, Compatible with BioMerieux Bottles D-21221 - Kurin Blood Culture Collection Set with Kurin Lock Technology, 21Ga Push Button Needle, Compatible with BD & Thermo Fisher Long-Neck Bottles D-21223 - Kurin Blood Culture Collection Set with Kurin Lock Technology, 23Ga Push Button Needle, Compatible with BD & Thermo Fisher Long-Neck Bottles T-21221 - Kurin Blood Culture Collection Set with Kurin Lock Technology, 21Ga Push Button Needle, Compatible with Thermo Fisher Short-Neck Bottles T-21223 - Kurin Blood Culture Collection Set with Kurin Lock Technology, 23Ga Push Button Needle, Compatible with Thermo Fisher Short-Neck Bottles
Classification Name(s):	Tubes, Vials, Systems, Serum Separators, Blood Collection
Classification Regulation(s):	862.1675
Device Class:	Class II
Product Code(s):	JKA
Advisory Panel:	Clinical Chemistry

Predicate Device				
Device Name	Regulation No.	Product Code	510(K) Number	Clearance Date
Kurin Blood Culture Collection Set	862.1675 - Tubes, Vials, Systems, Serum Separators, Blood Collection	JKA	K162233	12/23/2016

Device Description

The Subject Device is a sterile, single-use blood culture collection set. The blood collection set incorporates a venipuncture needle assembly that is connected with flexible tubing to a blood lock mechanism that is connected by flexible tubing to a blood collection holder. Blood collection is accomplished by inserting the venipuncture needle into the patient's peripheral vascular system. Blood will travel up the lumen into the blood lock mechanism where the initial draw of blood (approximately 0.15 ml) is held in a side chamber. The purpose of the side chamber is to automate the initial specimen diversion volume method (ISDVM). Once the side chamber volume is retained, the blood upon connection to a vacuum bottle continues to travel up the lumen to the blood collection holder into the attached blood culture bottle/vial.

The Subject Device's venipuncture needle assembly incorporates an active, semi-automatic needlestick safety design where the safety mechanism is activated via a button on the needle hub. When the safety mechanism is activated, a protective shield is deployed. It advances distally to cover the entire length, including the distal tip, of the venipuncture needle. The protective shield is locked in this position protecting the clinician/patient from needlestick injuries. Silicone coating is applied to the outside of the venipuncture needle, which aids in the insertion into the peripheral vascular system.

The Subject Device incorporates various blood collection holders to interact with various types of vacuum-based collection vials. (The blood collection holders were cleared in : K912563, K081229 and K950432)

Indications for Use

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 the prevention of needlestick injury if manually activated after the blood draw. For blood collection, the set also includes a blood collection holder for connection to vacuum-based collection vials.

Comparison of Technological Characteristics with Predicate Device

Comparison Table – Subject and Predicate Devices		
Comparison Feature	**Subject Device**	**Predicate Device**
Indications for Use	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 the prevention of needlestick injury if manually activated after the blood draw. For blood collection, the set also includes a blood collection holder for connection to vacuum-based collection vials. *Note: The change in the terminology from*	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 the prevention of needlestick injury if manually activated after the blood draw. For blood collection, the set also includes a safety shield and apparatus for connection to vacuum-based collection vials.

Comparison Table – Subject and Predicate Devices		
Comparison Feature	**Subject Device**	**Predicate Device**
	"safety shield and apparatus" to "blood collection holder" in the device component does not impact safety and effectiveness. Both terms are referencing the same device component. Three is no change in the device component design.	
Infusion indication	No	No
Single-use	Yes	Yes
Sterile	Yes	Yes
Method of sterilization, SAL	Ethylene Oxide, SAL 10^{-6}	Ethylene Oxide, SAL 10^{-6}
Needlestick mechanism type	Active, semi-automatic (i.e., push button) – Activation is achieved by depressing a spring activated button *Note: The change from the Predicate does not impact safety or effectiveness of the device. The push-button design provides protection prior to use with a needle tip protector and covers the needle upon activation after use. Performance testing in the 510(k) submission supports its safety.*	Active, manual (i.e. slide) – Activation is achieved by manually sliding a shield over the needle
Needle Gauge	21 & 23 *Note: Not offering the 25 Ga needle configuration does not impact the safety and effectiveness.*	21, 23, & 25
Needle Length	0.75 Inch	0.75 Inch
Device Length	12 Inches	12 Inches
Blood Collection Holder	Saf-T Holder Device (MFG: Smith Medical) Vacutainer One-Use Holder (MFG: BD) Monoject Safety Collection Device (MFG: Covidien) *Note: The additional blood collection holders does not impact the safety or effectiveness. Each blood collection holder works in the same and interfaces with the standard collection vial however each holder is designed to interface specifically with its manufacturer's culture collection bottle. All holders are design with shielding to the needle and are FDA cleared.*	Saf-T Holder Device (MFG: Smith Medical)
Sterile barrier packaging	Thermoform Tray/Tyvek Lidding Stock *Note: The change from the Predicate does not impact safety or effectiveness. The tray sterile barrier packaging was successfully tested to same transportation and seal integrity performance standards conducted*	Tyvek/Poly Pouch

Comparison Table – Subject and Predicate Devices		
Comparison Feature	**Subject Device**	**Predicate Device**
	with the predicate. Results are incorporated in the 510(k) submission and does not impact safety or effectiveness.	
Principles of operation	Venipuncture needle accesses the patient's vascular system then blood flows up to the blood lock mechanism where the first 0.15ml of blood is held in a side chamber and then blood is directed into the collection lumen. The collection container is connected to a blood collection holder where blood is collected. Needlestick safety mechanism is activated to protect against needlestick injuries.	Venipuncture needle accesses the patient's vascular system then blood flows up to the blood lock mechanism where the first 0.15ml of blood is held in a side chamber and then blood is directed into the collection lumen. The collection container is connected to blood collection holder where blood is collected. Needlestick safety mechanism is activated to protect against needlestick injuries.
Shelf-Life	6-month *Note: The difference in the shelf-life is not based on performance There is not impact to safety or effectiveness.*	1-year initially, currently 2-year

Summary of Evaluations Performed

The following evaluations were conducted to support the 510(k) submission:

- Sterilization (product adoption per AAMI TIR 28)
- Biocompatibility
- Pyrogenicity
- Performance/Stability
    - Needle Performance
        - Stiffness test
        - Resistance to breakage
        - Resistance to corrosion
    - Device Performance
        - Functionality
        - Leakage
        - Flow Rate
        - Needlestick Safety Mechanism
        - Tensile Strength
    - Packaging Integrity
        - Visual Inspection
        - Gross Leak (Bubble Emission)
        - Dye Penetration
        - Seal Strength (Peel)

Performance related to blood collection holder and compatibility with blood culture bottles

The following guidance documents and recognized performance standards were utilized in the development of the subject device:

- ISO 10993-1:2018 - Biological evaluation of medical devices - Part 1: Evaluation & testing within a risk process
- ISO 1135-3: 2016 - Transfusion Equipment for medical use – Part 3: Blood-taking sets for single use
- ISO 7864:2016 – Sterile hypodermic needles for single use – Requirements and test methods
- ISO 9626:2016 –- Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods
- ISO 23908:2011 – Sharps injury protection – Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters, and needles used for blood sampling
- ISO 11135:2014 – Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 11607-1:2006 – Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
- FDA Guidance – Medical Devices with Sharps Injury Prevention Features (8/9/2005)
- FDA Guidance – Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile (1/21/2016)

Conclusion

The Subject Device has demonstrated it is substantially equivalent to the commercially available predicate device based on the intended use and performance testing conducted on the subject device.