April 28, 2023

Kurin, Inc,
Neal Hartman
Regulatory Affairs/Quality Assurance
10840 Thornmint Road, Suite 111
San Diego, California 92012-7

Re: K220677
Trade/Device Name: Kurin Blood Culture Collection Set with Kurin Lock Technology
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA, FPA
Dated: March 27, 2023
Received: March 27, 2023

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,

David Wolloscheck, Ph.D.
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)*
K220677

Device Name
Kurin Blood Culture Collection Set with Kurin Lock Technology

Indications for Use *(Describe)*
The Kurin Blood Culture Collection Set is intended to obtain blood samples through the patient's vasculature via venipuncture or Peripheral IV (PIV) access. As it enters the Kurin Lock, blood initially fills a side channel then flows into the sample collection device (syringe or bottle) via an adjoining sampling channel to reduce blood culture contamination rates*.

When supplied with a pressure-rated extension set, the pressure-rated extension set is intended to be utilized separately with infusions systems to administer IV fluids, medications, blood and blood products into the patient's vascular system and may be safely used with power injectors at pressures up to 325 psi.

*The Kurin Blood Collection System is for use as a blood collection system and its Kurin Lock allows the specimen of blood from the patient to be sidelined prior to the collection of the test sample to reduce the frequency of blood culture contamination when contaminates are present in the initial blood sample compared to blood cultures drawn using standard practice without the Kurin Lock.

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 – K220677

Submitter Information

Company Name:	Kurin, Inc.
Company Address:	10840 Thornmint Road Suite 111 San Diego, CA 92127
Company Phone:	(888) 963-9056
Contact Person:	Neal Hartman Regulatory Affairs/ Quality Assurance nealhartman@kurin.com
Date:	April 27, 2023

Device Identification

Device Trade Name:	Kurin Blood Culture Collection Set with Kurin Lock Technology
Common Name:	Blood Collection Tubes, Vials, Systems, Serum Separators
Classification Name:	Blood specimen collection device
Classification Regulation(s):	862.1675
Device Class:	Class II
Primary Product Code:	JKA
Secondary Product Code:	FPA
Advisory Panel:	Clinical Chemistry

Identification of Predicate

Type	Device Name	Regulation No.	Product Code	510(K) Number	Clearance Date
Predicate	Steripath Micro Blood Collection System	880.5440	JKA, FPA	K200661	October 8, 2020

Purpose of Pre-Market Notification

To incorporate the blood culture contamination reduction claim in the indication for use statement.

Device Description

The Kurin Blood Culture Collection Set is a sterile, single-use device that includes a vasculature connection (i.e., winged needle, male luer connection), flexible tubing, blood lock mechanism, and blood culture bottle holder (when supplied). The blood culture bottle holder varies between device models. Refer to the primary labeling for the compatible culture bottle.

The Subject Device is intended to be used with the adult and pediatric population. The main purpose of the Subject Device is to obtain blood samples by transferring from the patient to a culture bottle or collection container.

Venipuncture sets incorporate a needle-safe feature that covers the needle prior to disposal to aid in the prevention of needlestick injury if activated after the blood draws. Venipuncture needles include 21 and 23 gauge.

Various Peripheral IV (PIV) sets incorporate a pressure-rated extension set with slide clamp that, when detached from the blood culture collection set, can be used for infusion purposes.

The unique technology with the Subject Device is the blood lock mechanism (i.e., Kurin Lock). Upon access to the patient's vasculature, the Subject Device uses the patient's blood pressure to push an initial portion of blood that could contain bacterial contaminants (e.g., skin plugs) into the side channel. After the side channel is filled, flow stops until a collection device (i.e., blood culture bottle, vacutainer tube, syringe) is attached. The attachment of a collection device draws additional blood through the Subject Device and into the collection device. The initial portion of blood in the side channel is not isolated from this additional incoming blood, the amount of contamination reaching the collection device is dramatically reduced.

The following table includes the product codes associated to the Subject Device:

Product Code	Device Configuration	Set Length	Culture Bottle Compatibility
D-11221	21Ga Standard Needle	12"	BD Thermo Fisher Long-Neck
D-11223	23Ga Standard Needle	12"	
D-21221	21Ga Push Button Needle	12"	
D-21223	23Ga Push Button Needle	12"	
D-PIV12	Peripheral Intravascular (PIV)	12"	
D-PIV18	Peripheral Intravascular (PIV) with detachable, pressure-rated, 6" (152mm) microbore extension set	18"	
M-11221	21Ga Standard Needle	12"	BioMerieux
M-11223	23Ga Standard Needle	12"	
M-21221	21Ga Push Button Needle	12"	
M-21223	23Ga Push Button Needle	12"	
M-PIV12	Peripheral Intravascular (PIV)	12"	
M-PIV18	Peripheral Intravascular (PIV) with detachable, pressure-rated, 6" (152mm) microbore extension set	18"	
S-PIV4	Short Peripheral Intravascular (PIV)	4"	None
S-PIV10	Short Peripheral Intravascular (PIV) with detachable, pressure-rated, 6" (152mm) microbore extension set	10"	
T-11221	21Ga Standard Needle	12"	Thermo Fisher Short-Neck
T-11223	23Ga Standard Needle	12"	
T-21221	21Ga Push Button Needle	12"	
T-1223	23Ga Push Button Needle	12"	
T-PIV12	Peripheral Intravascular (PIV)	12"	
T-PIV18	Peripheral Intravascular (PIV) with detachable, pressure-rated, 6" (152mm) microbore extension set	18"	

Indications for Use

The Kurin Blood Culture Collection Set is intended to obtain blood samples through the patient's vasculature via venipuncture or Peripheral IV (PIV) access. As it enters the Kurin Lock, blood initially fills a side channel then flows into the sample collection device (syringe or bottle) via an adjoining sampling channel to reduce blood culture contamination rates*.

When supplied with a pressure-rated extension set, the pressure-rated extension set is intended to be utilized separately with infusions systems to administer IV fluids, medications, blood and

blood products into the patient's vascular system and may be safely used with power injectors at pressures up to 325 psi.

*The Kurin Blood Collection System is for use as a blood collection system and its Kurin Lock allows the initial specimen of blood from the patient to be sidelined prior to the collection of the test sample to reduce the frequency of blood culture contamination compared to blood cultures drawn using standard practice without the Kurin Lock.

Substantial Equivalence Discussion

Comparison of Technological Characteristics with Predicate Devices

Comparison – Subject & Predicate Devices			
Comparison Feature	**Subject Device**	**Predicate Device**	**Comparison Comments**
510(k) No	K220677	K200661	N/A
Manufacturer	Kurin, Inc.	Magnolia Medical Technologies Inc	N/A
Device Name	Kurin Blood Culture Collection Set with Kurin Lock Technology	Steripath Micro Blood Collection System	N/A
Common Name	Blood Collection Set	Blood Collection Set	Identical
Indication for Use	The Kurin Blood Culture Collection Set is intended to obtain blood samples through the patient's vasculature via venipuncture or Peripheral IV (PIV) access. As it enters the Kurin Lock, blood initially fills a side channel then flows into the sample collection device (syringe or bottle) via an adjoining sampling channel to reduce blood culture contamination rates*. When supplied with a pressure-rated extension set, the pressure-rated extension set is intended to be utilized separately with infusions systems to administer IV fluids, medications, blood and blood products into the patient's vascular system and may be safely used with power injectors at pressures up to 325 psi. *The Kurin Blood Collection System is for use as a blood collection system and its Kurin Lock allows the initial specimen of blood from the patient to be sidelined prior to the collection of the test sample to reduce the frequency of blood culture contamination compared to blood cultures drawn using standard practice without the Kurin Lock.	The Steripath Micro Blood Collection System is a system to draw blood for in vitro diagnostic testing. The Steripath Micro Blood Collection System is indicated for use as a blood collection system that diverts and sequesters the initial specimen prior to collection of a subsequent test sample to reduce the frequency of blood culture contamination when contaminants are present in the initial blood sample compared to blood cultures drawn with standard procedure without manual diversion. Additionally, components of the system may be used for infusion following sample collection after disconnection of the Initial Specimen Diversion Device® (ISDD).	The indication for use statements is generally identical in nature, however the Subject Device provides additional details, which are associated to various product configurations. All information included in the Subject Device's indication for use statement, except for the blood culture contamination reduction claim, have been cleared in other 510(k) submissions (K191832, K181895). The blood culture contamination reduction claim is supported with literature review and bench testing (particulate reduction) evaluated in this 510(k) review.
Infusion indication	Yes, only with the detached pressure-rated extension set	Yes	Identical

Comparison – Subject & Predicate Devices			
Comparison Feature	**Subject Device**	**Predicate Device**	**Comparison Comments**
Single-use	Yes	Yes	Identical
Sterile	Yes	Yes	Identical
Method of sterilization, SAL	Ethylene Oxide, 10^{-6}	Gamma, 10^{-6}	The sterilization methods are different, Subject Device was validated to ISO 11135. Safety was demonstrated through the sterilization validation.
Non-pyrogenic	Yes	Yes	Identical
Needle Gauge	21, 23 (with associated product configurations)	None	Performance associated with venipuncture needles was verified in K191832, which performance testing was conducted per ISO 7864, ISO-1135-3, and ISO-23908. Testing demonstrated the Subject Device's safety.
Needle Length	0.75 inch (with associated product configurations)	N/A	
Initial draw of blood sidelined	0.15 ml	0.6-0.9 ml	The Subject Device sidelined blood volume is less than the predicate device. The adequacy of the volume sidelined was reviewed in this 510(k) submission with peer reviewed articles that demonstrated blood culture contamination reductions with the Subject Device. Bench testing (particulate reduction) was also conducted to demonstrate the performance of the blood lock mechanism.
Blood Collection Holder	Saf-T Holder Device (MFG: Smith Medical) Vacutainer One-Use Holder (MFG: BD) Monoject Safety Collection Device (MFG: Covidien)	Custom	The Subject Device provides different configurations of blood collection holders to accommodate the various culture bottles on the market. Compatibility and functionality were confirmed with simulated used functional evaluations. Effectiveness was demonstrated through these evaluations.

Summary of Evaluations Performed

The following evaluations were conducted to support the blood culture contamination claim for the Subject Device in this submission:

- Scientific Literature Review
    - "*Innovation for Reducing Blood Culture Contamination: Initial Specimen Diversion Technique*" Richard G. Patton
        - Diversion devices were not utilized in the documented study
        - Provides information on skin/tissue fragments created during venipuncture contain microbial contaminants that are present in initial specimen volume
        - Does not identify the absolute minimum effective volume for blood contamination rates reduction
        - Significant improvement in contamination with a volume of ≥0.5, ≤2 ml was with a 16-gauge needle, which has approximately 5 times greater volume than a 21-GA needle: one should expect less contamination with the smaller 21-GA needle.
    - *"Asynchronous Testing Of 2 Specimen diversion - Devices to Reduce Blood Culture Contamination: A Single-Site Product Supply Quality Improvement Project"* Monica Arenas
        - Conducted at Central Texas Veterans Health Care System (CTVHCS) between November 2017 to February 2019, where a total of 4300 blood samples were taken between the control and two (2) blood culture–diversion devices. Device A is manufactured by Magnolia Medical Technologies and isolates the first 1-2 mL of blood and Device B is manufactured by Kurin, Inc. and passively diverts less than 0.15 mL of blood. The control was blood sampling without a blood culture-diversion device.
        - Model estimated that the mean incidence of contaminated draws per month in the device A group was 0.29 (0.14-0.55) times the incidence of contaminated draws in the control group. The estimated mean incidence of contaminated draws in device B group was 0.23 (0.13-0.37) times the incidence of contaminated draws in the control group.
        - Evaluation demonstrates equivalent performance between the Magnolia's diversion device and the Subject Device, as it relates to blood contamination rate reduction.
- Performance
    - Particle Reduction through Device (T=0, T=2 Year)

Safety and performance evaluation for the Subject Device were performed in the previous submissions (K191832, K181895). Evaluations assessed include the following:

- Sterilization (ISO 11135, ISO 10993-7)
- Biocompatibility (ISO 10993-1, Venipuncture Configuration – Externally communicating medical device with circulating blood contact for limited exposure; Extension Set Configuration - Externally communicating medical device with indirect blood path contact for prolong exposure)
    - Cytotoxicity
    - Sensitization
    - Irritation or Intracutaneous reactivity

    - Systemic toxicity
    - Hemocompatibility
    - Material Mediated Pyrogen
- Performance/Stability
    - Needle Performance (ISO 9626)
        - Stiffness test
        - Resistance to breakage
        - Resistance to corrosion
    - Device Performance (ISO 1135-3, ISO 23908, ISO 7864, ISO 8536-9)
        - Functionality
        - Leakage
        - Flow Rate
        - Needlestick Safety Mechanism (ISO 23908)
        - Tensile
        - Burst Pressure
    - Packaging Integrity (ISO 11607)
        - Visual Inspection
        - Gross Leak (Bubble Emission)
        - Dye Penetration
        - Seal Strength (Peel)
- Human Factors (FDA Guidance, Applying Human Factors & Usability Engineering to Medical Devices)

The following guidance documents and recognized performance standards were utilized to support the Subject Device for this submission:

- AAMI/ANSI/ISO 15223-1:2016 - Medical devices - symbols to be used with medical devices labels, labeling, and information to be supplied - part 1: general requirements
- 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)

Clinical Testing – Not applicable

Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Subject Device is substantially equivalent to the commercially available predicate.