



Food and Drug Administration
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December 23, 2016

Pathway LLC.
c/o Mark Job
Regulatory Technology Services LLC
1394 25th Street North West
Buffalo, MN 55313

Re: K162233

Trade/Device Name: Kurin Blood Culture Collection Set
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Set
Regulatory Class: Class II
Product Code: JKA
Dated: December 1, 2016
Received: December 8, 2016

Dear Mr. Mark Job:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH 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

Indications for Use

510(k) Number (if known)

K162233

Device Name

Kurin Blood Culture Collection Set

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 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

- A. Submitter:** Pathway LLC, on behalf of Calliope Solutions, Inc.
- B. Date Prepared:** September 7, 2016
- C. Address:** 8779 Cottonwood Ave, Suite 105, Santee CA 92071
- D. Corporate Contact:** David Stroup
- E. Submission Contact:** Emily Davis, Quality Consultant
Pathway LLC
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Santee CA 92071
Ph: 949.636.4621
Email: erbakersd@gmail.com
- F. Trade Name:** Kurin Blood Culture Collection Set
- G. Predicate Device(s):** (1) BD Vacutainer Blood collection set and Safety-Lok blood collection set (K980414)

(2) Smith Medical Saf-T Holder Adapter (K923090)
- H. Common Name:** Venous Blood Collection Device
- I. Classification:** Class II

Regulation Number	Product Code	Classification Name	Device Class
862.1675	JKA	Blood Specimen Collection Device	II

J. Device Description

The Kurin device is a sterile, single use blood culture collection set. The Kurin includes a winged needle with flexible tubing and an attached vial adapter intended for venipuncture to obtain blood culture samples. Kurin is identical in every way to existing sets used to collect blood culture samples except for the insertion into the tubing of the Kurin blood capture chamber. The Kurin blood capture device sequesters the initial draw of blood upon initial venipuncture. The set is provided with a safety shield for covering the used needle prior to disposal. The amount of blood diverted is very small, estimated at a fraction of 1 ml.

Below is a table with the three models and sizes of the subject device's that intend to be marketed.

Model	Measurement (mm)			Weight (g)	Tubing	Gauge
	H	D	W			
K-11221	31mm	13mm	6.45mm	15.7g	12 in	21 Gauge
K-11223	31mm	13mm	6.45mm	15.7g	12 in	23 Gauge
K-11225	31mm	13mm	6.45mm	15.7g	12 in	25 Gauge

K. Intended 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 safety shield and apparatus for connection to vacuum based collection vials.

L. Predicate Device(s)

The Kurin device is substantially equivalent to the following FDA cleared predicate devices:

Predicate #1

510(k) Number: K980414
 Trade Name: Vacutainer Brand Safety-Lok Blood Collection Set
 Model Multiple
 Manufacturer: **Becton Dickinson**
 Common/Usual Name: Accessory to: Tubes, Vials, Systems, Serum
 Separators, Blood Collection
 Regulation Number: 862.1675
 Product Codes: JKA
 Classification: II

Predicate #2

510(k) Number: K923090
 Trade Name: Saf-T Holder Multi Sample Luer Adapter
 Manufacturer: **Smiths Medical**
 Common/Usual Name: Tubes, Vials, Systems, Serum Separators, Blood
 Collection
 Regulation Number: 862.1675
 Product Codes: JKA
 Classification: II

M. Substantial Equivalence

Feature	Proposed Device The "Kurin"	VACUTAINER BRAND SAFETY-LOK BLOOD COLLECTION SET MODEL MULTIPLE K980414	SAF-T HOLDER MULTI SAMPLE LUER ADAPTER W/ BLOOD K923090
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 safety shield and apparatus for connection to vacuum based collection vials.	The VACUTAINER® brand blood collection sets and Safety-Lok™ blood collection set is a winged blood collection needle and flexible tubing for venipuncture to collect blood specimens from patients or monitoring blood pressure. The Safety-Lok™ blood collection set also contains a needle safety shield which minimizes the possibility of needlesticks if manually activated following blood collection. The VACUTAINER® brand blood collection sets and Safety-Lok™ blood collection set is also recommended for use in patients with small veins. The VACUTAINER® brand blood collection sets and Safety-Lok™ blood collection set is also indicated for the intravenous administration of fluids and may be used for any patient	The Saf-T HOLDER® Blood Culture device is intended for use as a culture bottle or vacuum tube holder that can be attached to a female Luer connector of the Saf-T Wing® blood collection set or equivalent.

		population with consideration given to patient size, appropriateness for the solution being infused and duration of therapy.	
Device Description	The Kurin set is a sterile, single use blood culture collection set. The Kurin includes a winged needle with flexible tubing and an attached vial adapter intended for venipuncture to obtain blood culture samples. Kurin is identical in every way to existing sets used to collect blood culture sample except for the insertion into the tubing of the Kurin blood capture chamber. The Kurin blood capture device sequesters the initial draw of blood upon initial venipuncture. The set is provided with a safety shield for covering the used needle prior to disposal. The amount of blood diverted is very small, estimated at a fraction of 1 ml.	The Vacutainer Brand Blood Collection sets and safety-Lok blood collection set is a sterile winged blood collection needles with flexible tubing and a female luer adapter manufactured by Becton Dickinson Vacutainer Systems, Sumter, South Carolina. The Safety-Lok Blood Collection set is provided with a safety shield for covering the used needle prior to disposal. A male luer adapter is provided on specific reorder numbers. A male luer adapter contains a non-patient needle end for puncturing the stopper of an evacuated blood collection tube. Those without a male luer adapter are provided a protective cap on the end of the female luer adapter.	The Saf-T HOLDER® Blood Culture device is a sterile multi-sample luer adapter for venous blood sampling that includes a blood culture bottle holder with a fixed back end needle, male luer threaded connector and vacuum tube adapter.
Product Code	JKA	JKA	JKA
Patient Interface	Used only by trained professionals in a medical setting	Used only by trained professionals in a medical setting	Used only by trained professionals in a medical setting
Materials and Chemical Composition			
Kurin Materials	Makrolon Polycarbonate	unknown, medical grade plastic	unknown, medical grade plastic
Tubing	Transparent Flexible tubing	Substantially equivalent	NA since this is just the adapter
Adapter	Male or Female Luer	Substantially equivalent	Substantially equivalent
Performance/Design Specifications			
Sequesters initial blood	Yes	No	No
Single Use Device	Single Use	Single Use	Single Use
Indicated for Infusion	No	Yes	No
Needle Gauge	21, 23, 25 Gauge	21, 23, 25 Gauge	Standard vial adapter
Labeled Pyrogen Free	No	Yes	No
Sterilization	Yes, EtO	Yes, EtO	Yes, EtO

Expiration/Shelf Life	1 year (with protocols up to 3 years)	3 years	5 years
Size (LxWxH)	21G, ¼ inch, 12 inch tubing,0.337 volume 23G, ¼ inch, 12 inch tubing,0.332 volume 25G, ¼ inch, 12 inch tubing,0.331 volume	21G, ¼ inch, 12 inch tubing,0.337 volume 23G, ¼ inch, 12 inch tubing,0.332 volume 25G, ¼ inch, 12 inch tubing,0.331 volume	2.5 in x 2 in
Principles of Operation	The winged needle is used to access the patient’s blood stream, the safety shield is used cover the needle after collection, the kurin component sequesters the initial sample of blood and the vial adapter is used to interface with a vacuum tube or culture bottle. There is no energy source, the subject device fills with blood by differences in pressure gradient.	The winged needle is used to access the patient’s blood stream, the safety shield is used cover the needle after collection, the tubing and luer connector are used to attach to a vial adapter or infusion set. There is no energy source, the subject device fills with blood by differences in pressure gradient.	Cylindrical holder for vacuum bottle or tube placement with threads that are compatible with blood collection needles and luers.
Biocompatibility	Conforms with ISO 10993	Conforms with ISO 10993	Conforms with ISO 10993

N. Non-Clinical Testing

All testing met specifications for the subject device and demonstrates substantial equivalence to the predicates.

1. Sterilization – The Kurin device is sterilized using a validated EO sterilization process which complies with ISO 11135-1:2006 Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
2. Aging/Shelf Life Test– The Kurin device was validated to achieve 1-year shelf life with protocols for up to 3 years of shelf life for sterility and performance.
3. Functional, Leakage and Tensile Test – The Kurin set confirmed the addition of the Kurin device shows no compromise to the function of the blood collection device in regards to functionality. With the addition of the device the product does not leak and passed tensile testing in accordance with sections 5.2 and 5.3 of ISO 1135-3 - Transfusion equipment for medical use -- Part 3: Blood-taking set for single use.
4. Packaging Integrity and Shipping Test – This test was completed and the Kurin device passed all tests in accordance with ISO 11607 and ASTM D4169-14.
5. Biocompatibility Tests – The Kurin device passed two types of biocompatibility tests: the MEM Elution Test demonstrated that no leachables are present from the system and the IVH Blood Count Test which demonstrated that the blood path did not adversely affect the constituents of blood exposed to the systems fluid path.
6. User Verification Test - Testing was conducted to evaluate if the instructions for use were easy to understand and the functionality of the device.
7. Flow Rate Test – Testing verified that the addition of the Kurin Device into the tubing of the FDA cleared BD Vacutainer® brand blood collection set and Safety-Lok™ Blood Collection set did not change the flow rate of liquid passing through the device.

O. Clinical Testing

No clinical test data is required of the Proposed Device.

P. Conclusion

The above information and tests conducted demonstrate that the Subject Device is substantially equivalent to the identified predicates.