December 4, 2023

The Monarch Company
Pooja Kannam
Director of Quality and Regulatory affairs
4000 Eagle Point Corporate Drive
Birmingham, Alabama 35242

Re: K232308
Trade/Device Name: Monarch Blood Collection Set
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: November 2, 2023
Received: November 2, 2023

Dear Pooja Kannam:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

David Wolloscheck, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232308

Device Name
Monarch Blood Collection Set

Indications for Use *(Describe)*
The Monarch Safety Blood Collection Set is a sterile, multi-sample, single use fixed winged blood collection set. The device is indicated for general medical use in Healthcare Facilities by medical professionals with the patient population to include both adolescent and adult patients. The Monarch Blood Collection Set is intended to be used with evacuated blood collection tubes and/or blood culture bottles. The Monarch Blood Collection device is to remain under direct supervision of a medical professional during use.

The Monarch Blood Collection set includes a safety feature to prevent accidental needlestick injury during normal handling and disposal. The safety feature is initiated by full manual retraction of the needle from the venipuncture site to prevent accidental needlesticks during handling and disposal. The Monarch Blood Collection set is not intended for infusion, IV administration, or transfusion.

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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K232308: 510K summary For Monarch Blood Collection set

1. Submission date

12/01/2023

2. Submitter Information

The Monarch Company, LLC

4000 Eagle point Corporate Drive

Birmingham, AL, 35242-1900

Contact Information	Pooja Priyanka Kannam
Phone Number	901-598-1429
Email Address	poojak@hmg-distribution.com

3. Device Information

Trade/Proprietary name	Monarch Blood Collection Set
Common Name of device	Blood Collection Set
Product Code	JKA
Regulatory Class	II
Regulation Number	862.1675
Regulation name	Blood Specimen Collection Device
Review Panel	Clinical Chemistry

4. Predicate Device

K213718	SOL-GUARD™ Safety Pull-Button Blood Collection Set

5. Device Description

The Monarch Blood Collection Set is a sterile, single-use, winged needle with tubing and luer connector. Each Monarch Blood Collection device is individually wrapped in a blister pouch. Monarch Blood collection sets include configurations for three (3) needle gauges (21, 23, 25) each with a tubing length of 12 inches. All the models are included with the back-end needle and a vacutainer holder.

A blood collection assembly, comprises of a needle assembly fixedly coupled to a finger-activated actuator and tubing, the needle assembly comprising a needle; a hub including a channel in a top surface of the hub, a proximal end and a distal end, the distal end

defining a cavity and a distal passageway, the channel slidably engaging the finger-activated actuator such that when the finger-activated actuator is moved from a first position at a distal end of the hub to a second position toward a proximal end of the hub; an active closure assembly including a door and a biasing mechanism positioned within the cavity such that when the finger-activated actuator is in the second position, the biasing mechanism operates to move the door along the cavity to contact the needle; and a support wall positioned adjacent the cavity such that, when the finger-activated actuator is in the second position, the needle contacts the support wall.

Nature of contact duration for the device is limited exposure ≤ 24 h. Nature of body contact is external communicating device: Circulating blood.

The Monarch Blood Collection set is available in the following models,

Model Name	Configuration
M2112	21g, 3/4" Needle, 12" tubing, without luer adapter
M2312	23g, 3/4" Needle, 12" tubing, without luer adapter
M2512	25g, 3/4" Needle, 12" tubing, without luer adapter

monarch™
blood collection sets

6. Indications For Use

Characteristic	Subject Device Monarch Safety blood Collection Set	Predicate Device SOL-GUARD™ Safety Pull-Button Blood Collection Set K213718
Indications for Use	The Monarch Safety Blood Collection Set is a sterile, multi-sample, single use fixed winged blood collection set. The device is indicated for general medical use in Healthcare Facilities by medical professionals with the patient population to include both adolescent and adult patients. The Monarch Blood Collection Set is intended to be used with evacuated blood collection tubes and/or blood culture bottles. The Monarch Blood Collection device is to remain under direct supervision of a medical professional during use. The Monarch Blood Collection set includes a safety feature to prevent accidental needlestick injury during normal handling and disposal. The safety feature is initiated by full manual retraction of the needle from the venipuncture site to prevent accidental needlesticks during handling and disposal. The Monarch Blood Collection set is not intended for infusion, IV administration, or transfusion.	The SOL-GUARD™ Safety Pull- Button Blood Collection Set is a sterile, multi-sample, single-use fixed winged blood collection set intended for venipuncture to obtain blood specimens from patients. When used without the male Luer adapter, the device allows the clinician to obtain blood sampling to the female hub with a syringe, if necessary, or can be used for short-term (up to 2 hours), single infusions with consideration given to patient size and appropriateness for the solution being infused. The device is not to be left in place and remain under the direct supervision of a clinician. The recommended use of the device is to activate the needle safety feature prior to removal the venipuncture site. The retraction of the intravenous (IV) end of the needle aids in the prevention of accidental needlesticks injury.
Prescription Only or Over the Counter	Prescription Only	Prescription Only

7. Comparison Table for Technological Characteristics

Specification	Subject Device Monarch Safety blood Collection Set	Predicate Device SOL-GUARD™ Safety Pull-Button Blood Collection Set K213718	Comments (Same or Different)
Indicated for infusion	No	Yes	Different. Subject device should not be used for infusion. The subject device is intended for a subset of the predicate device intended use. The difference does not raise new or different questions of safety and effectiveness.
Single use	Yes	Yes	Same
Activation of safety mechanism	Finger Tab That pulls back (Slide actuated)	Pull Button	Subject device has a different mechanism to retract the needle. The needle safety feature was tested in accordance with ISO23908:2011. This difference does not impact the safety and effectiveness of the subject device.
Components:			
Needle Gauge Sizes	21G, 23G, 25G	21G, 23G, 25G	Same
Needle Diameter ID	Thin Wall	Thin Wall	Same
Tubing Length	12”	7” and 12”	Different. Only one size of tubing is provided by Monarch. The device was adequately tested in accordance with ISO 80369-7 :2021. This difference does not impact the safety and effectiveness of the subject device.
Needle Length	0.75”	0.75”	Same
Needle Point	3-bevel	3-bevel	Same
Performance:			
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}	Same
Non-pyrogenic	Yes	Yes	Same
Shelf life	5 years	3 years	Shelf life of the subject device is 5 years. Device performance was conducted after 5 years of aging to demonstrate the device performed to specification over the 5-year shelf life. The difference does not raise any new or different questions of safety

Specification	Subject Device Monarch Safety blood Collection Set	Predicate Device SOL-GUARD™ Safety Pull-Button Blood Collection Set K213718	Comments (Same or Different)
			and effectiveness.
Materials:			
Needle	Stainless Steel	Stainless Steel	Same
Needle/Hub Glue	UV cure Adhesive	Epoxy Glue	The needle was tested in accordance with ISO 7864:2016 and ISO9626:2016. This difference does not impact the safety and effectiveness of the subject device.
Spring	Stainless Steel	Stainless Steel	Same
Needle Hub	MethylMethacrylonitrile Butadiene Styrene	Low Density Polyethylene	Different material: however, ISO10993-1 testing demonstrates biocompatibility of the device. There is no impact to safety and effectiveness caused by the subject device
Sliding Button	Polypropylene	Polycarbonate	Different material: however, ISO10993-1 testing demonstrates biocompatibility of the device. There is no impact on the safety and effective caused by the different type of material used by the subject device.
Door	Polyoxymethylene	N/A	Different. Predicate device does not have a door; however, device performance and biocompatibility testing demonstrate this difference does not impact the safety and effectiveness of the subject device.
Needle Protector	Polypropylene	Low Density Polyethylene	Slightly different for the density of the material; however, device performance and biocompatibility testing demonstrate there is no impact on the safety and effectiveness of the subject due to the density difference of the material.
Wings	EthylVinyl Acetate	Polyvinyl Chloride	Different material: however, ISO10993-1 testing demonstrates biocompatibility of the device. This difference does not impact the safety and effectiveness of the subject device.
Housing A	Acrylonitrile Butadiene Styrene	Polycarbonate	Different material: however ISO10993-1 testing demonstrates biocompatibility of the device. This difference does not impact

Specification	Subject Device Monarch Safety blood Collection Set	Predicate Device SOL-GUARD™ Safety Pull-Button Blood Collection Set K213718	Comments (Same or Different)
			the safety and effectiveness of the subject device.
Housing B	N/A	Polycarbonate	Subject device does not have housing B. This does not impact the safety or effectiveness of the Subject device.
Tubing	Polyvinyl Chloride	Polyvinyl Chloride	Same
Female Luer Lock Connector	MethylMethacrylonitrile Butadiene Styrene	Polyvinyl Chloride	Different material; however ISO10993-1 testing demonstrates biocompatibility of the device. This difference does not impact the safety and effectiveness of the subject device.
Luer Adapter	MethylMethacrylonitrile Butadiene Styrene	Luer Adapter Hub: Polypropylene Needle Cap: Low Density Polyethylene Needle: Stainless Steel Rubber Sleeve: Polyisoprene Rubber	Different material; however ISO10993-1 testing demonstrates biocompatibility of the device. This difference does not impact the safety and effectiveness of the subject device.
Holder	CLEARBLEND 165 (an impact modified styrene acrylic copolymer blend)	Polypropylene	Different material; however ISO10993-1 testing demonstrates biocompatibility of the device.. This difference does not impact the safety and effectiveness of the subject device.

8. Testing Summary for the Non-Clinical testing

Standard or a guidance reference	Description of the standard or guidance	
ISO 11607-1 Second Edition 2019-02	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	
ISO 11135 Second Edition 2014-07-15 Amendment 1 2018-10	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices — Amendment 1: Revision of Annex E, Single batch release	
ISO 7864 Fourth edition 2016-08-01	Sterile hypodermic needles for single use - Requirements and test methods	

Standard or a guidance reference	Description of the standard or guidance	
ISO 80369-7 Second edition 2021-05	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications	
ISO 80369-20 First edition 2015-05-15	Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods	
ISO 23908 First edition 2011-06-11	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 9626 Second edition 2016-08-01	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods	a. Acute Systemic Toxicity b. Complete Blood Count and Leukocyte study c. Cytotoxicity Study d. Genotoxicity Study: Bacterial reverse mutation e. Genotoxicity Study: In-Vitro mammalian chromosomal Aberration f. Hemolysis Study g. Intracutaneous reactivity study h. Material mediated Pyrogenicity Study i. Skin sensitization Study j. Thrombosis Study (Platelet Count and Morphology by SEM image)
ANSI AAMI ST72:2019 / USP <Chapter 161>	Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing	
ISO 11737-2 Third Edition 2019-12 / USP <Chapter 71>	Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	
USP Chapter 788	Particulate matter in Injection	
ISO 10993-3 Third Edition 2014-10	Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	
ISO 10993-33 First Edition 2015-03	Biological evaluation of medical devices — Part 33: Guidance on tests to evaluate genotoxicity — Supplement to ISO 10993-3	
ISO 10993-4 Third Edition 2017-04	Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood	
ISO 10993-5 Third edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	

Standard or a guidance reference	Description of the standard or guidance	
ISO 10993-10 Fourth edition 2021-11	Biological evaluation of medical devices - Part 10: Tests for skin sensitization	
ISO 10993-11 Third edition 2017-09	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	
ISO 10993-23 First Edition 2021-01	Biological evaluation of medical devices — Part 23: Tests for irritation	
ISO 10993-17 First Edition 2002-12-01	Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances	
ISO 10993-7 Second Edition 2008-10-15 Amendment 1 2019-12	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals — Amendment 1: Applicability of allowable limits for neonates and infants	
ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices	
ASTM F1886/F1886M-16	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection	
ASTM F2096-11R19	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	
ASTM F88/F88M-21	Standard Test Method for Seal Strength of Flexible Barrier Materials	
ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	
ISTA-3A 2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or less Note: Post-Transportation testing was also performed on the packaging for Visual Inspection, Seal Strength (tensile) test, and Die Penetration testing.	

9. Clinical Testing

Clinical studies are not required to demonstrate substantial equivalence to the predicate device.

10. Conclusion

The differences between the predicate device and the subject device do not raise new or different questions of safety or effectiveness. The Monarch Blood Collection Set is substantially equivalent to the SOL-GUARD Safety Pull Button Collection Set, K213718 with respect to indications for use, and technological characteristics.