November 30, 2022

Magnolia Medical Technologies
Donna Matuizek
Senior Director, Quality and Regulatory
200 West Mercer Street, Suite 500
Seattle, Washington 98119

Re: K222299
Trade/Device Name: Steripath® Micro Blood Collection System
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA, FPA
Dated: October 28, 2022
Received: October 31, 2022

Dear Donna Matuizek:

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.
For Joyce M. Whang, Ph.D.
Acting 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)*
K222299

Device Name
Steripath® Micro Blood Collection System

Indications for Use *(Describe)*
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®).

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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K222299 510(k) Summary

Date Prepared: November 16, 2022

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Trade Name: Steripath® Micro Blood Collection System

Common Name: Blood Collection Tubes, Vials, Systems, Serum Separators

Regulation Name: Blood Specimen Collection Device

Regulation Number: 21 CFR 862.1675

Regulatory Class: Class II

Product Code: JKA and FPA

Primary Predicate: Steripath Micro Blood Collection System (K200661)

5.1. Device Description:

The device, Steripath® Micro Blood Collection System, is a system to draw blood for in vitro diagnostic testing. The purpose of this submission is to expand the product line to include inlet components with the BD Venipuncture® UltraTouch™ Push Button Needle, outlet components with a transfer adapter, and universal models with no inlet component.

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.

The device sequesters and diverts 0.5 - 1.0 mL of the initial specimen of blood (potentially contaminated) into a diversion chamber. Once diversion is complete, a subsequent blood sample flows through a second pathway within the device and is collected either directly into a culture bottle (not provided by Magnolia Medical Technologies), or into a syringe that is used to inoculate culture bottles. Additionally, components of the system may be used for infusion after disconnection of the Initial Specimen Diversion Device® (ISDD®).

The Steripath® Micro Blood Collection System, needle configurations, for the subject device are manufactured using non-sterile BD UltraTouch® needles, which are equivalent to the commercially available BD UltraTouch® Push Button™ Blood Collection Set (K212724), except for the sterilization step. The Steripath® Micro Blood Collection System and UltraTouch® needles have the same intended use. Incorporation of the needle with the ISDD® functions on the same technological characteristics and principles of operation with the difference that the subject device leverages the Initial Specimen Diversion Technology® (ISDT) and mechanically sequesters the initial specimen of blood. Inclusion of this technology does not raise any added questions of safety or effectiveness.

The different configurations of the Steripath® Micro Blood Collection System are made available by using different combinations of the inlet and outlet accessories. Proposed configurations are listed in Table 5.1.

Table 5.1 Steripath Micro Blood Collection System Configurations

Model No.	Base Assembly	Description	Inlet	Outlet
4000-EN	P00818-001	Steripath Micro Blood Collection System - 9in Luer, Wide Neck Transfer Adapter (TA)	Luer Extension, ICU Medical, 9" Length	Wide Neck Transfer Adapter Assembly
4000-21UT-EN	P00818-001	Steripath Micro Blood Collection System - 21G UltraTouch, Wide Neck TA	Blood Collection Set, Push Button, UltraTouch, 21G, BD, Non-Sterile	Wide Neck Transfer Adapter Assembly
4000-23UT-EN	P00818-001	Steripath Micro Blood Collection System - 23G UltraTouch, Wide Neck TA	Blood Collection Set, Push Button, UltraTouch, 23G, BD, Non-Sterile	Wide Neck Transfer Adapter Assembly
4000-UN-EN	P00818-001	Steripath Micro Blood Collection System - Universal, Wide Neck TA	No inlet	Wide Neck Transfer Adapter Assembly
40BD-EN	P00818-001	Steripath Micro Blood Collection System - 9in Luer, Long Neck TA	Luer Extension, ICU Medical, 9" Length	Long Neck Transfer Adapter Assembly
40BD-21UT-EN	P00818-001	Steripath Micro Blood Collection System - 21G UltraTouch, Long Neck TA	Blood Collection Set, Push Button, UltraTouch, 21G, BD, Non-Sterile	Long Neck Transfer Adapter Assembly

Model No.	Base Assembly	Description	Inlet	Outlet
40BD-23UT-EN	P00818-001	Steripath Micro Blood Collection System - 23G UltraTouch, Long Neck TA	Blood Collection Set, Push Button, UltraTouch, 23G, BD, Non-Sterile	Long Neck Transfer Adapter Assembly
40BD-UN-EN	P00818-001	Steripath Micro Blood Collection System - Universal, Long Neck TA	No inlet	Long Neck Transfer Adapter Assembly
4005-EN	P00818-001	Steripath Micro Blood Collection System - 7in Luer, 5mL Syringe	Luer Extension, ICU Medical, 7” Length	Syringe, 5mL, Polypropylene
4005-21UT-EN	P00818-001	Steripath Micro Blood Collection System - 21G UltraTouch, 5mL Syringe	Blood Collection Set, Push Button, Ultra-Touch, 21G, BD, Non-Sterile	Syringe, 5mL, Polypropylene
4005-23UT-EN	P00818-001	Steripath Micro Blood Collection System - 23G UltraTouch, 5mL Syringe	Blood Collection Set, Push Button, Ultra-Touch, 23G, BD, Non-Sterile	Syringe, 5mL, Polypropylene
4005-UN-EN	P00818-001	Steripath Micro Blood Collection System - Universal, 5mL Syringe	No inlet	Syringe, 5mL, Polypropylene
4010-EN	P00818-001	Steripath Micro Blood Collection System - 7in Luer, 10mL Syringe	Luer Extension, ICU Medical, 7” Length	Syringe, 10mL, Polypropylene

Model No.	Base Assembly	Description	Inlet	Outlet
4010-21UT-EN	P00818-001	Steripath Micro Blood Collection System - 21G UltraTouch, 10mL Syringe	Blood Collection Set, Push Button, Ultra-Touch, 21G, BD, Non-Sterile	Syringe, 10mL, Polypropylene
4010-23UT-EN	P00818-001	Steripath Micro Blood Collection System - 23G UltraTouch, 10mL Syringe	Blood Collection Set, Push Button, Ultra-Touch, 23G, BD, Non-Sterile	Syringe, 10mL, Polypropylene
4010-UN-EN	P00818-001	Steripath Micro Blood Collection System - Universal, 10mL Syringe	No inlet	Syringe, 10mL, Polypropylene
4020-EN	P00818-001	Steripath Micro Blood Collection System - 7in Luer, 20mL Syringe	Luer Extension, ICU Medical, 7” Length	Syringe, 20mL, Polypropylene
4020-21UT-EN	P00818-001	Steripath Micro Blood Collection System - 21G UltraTouch, 20mL Syringe	Blood Collection Set, Push Button, Ultra-Touch, 21G, BD, Non-Sterile	Syringe, 20mL, Polypropylene
4020-UN-EN	P00818-001	Steripath Micro Blood Collection System - Universal, 20mL Syringe	No inlet	Syringe, 20mL, Polypropylene

5.2. Intended Use/ Indication for Use:

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®).

5.3. Technological characteristics

The Steripath® Micro Blood Collection System is a pre-assembled single use, sterile, mechanical device that diverts and sequesters the initial 0.5mL to 1.0mL of blood from the patient. The device consists of the proprietary Initial Specimen Diversion Device® (ISDD®) made of injection molded, medical grade plastics, an inlet component, and an outlet component. The inlet components include needles and Luer extensions for interfacing with patients while the outlet components include syringes and transfer adapters for interfacing to blood culture bottles. The device family also includes no-inlet configurations which requires a compatible inlet to be attached prior to use.

Venous blood access is obtained by venipuncture or connecting to the peripheral IV catheter hub using the standard blood collection procedure. The negative pressure created by actuating the syringe plunger or by connecting the culture bottle to the transfer adapter, causes blood to flow into the C-shaped diversion chamber. When the C-shaped chamber is filled with blood, the button on the side of the diversion chamber is depressed to isolate the initial specimen and a new sterile pathway opens to collect a subsequent specimen for blood culture or other analysis.

The predicate device – the three (3) previously cleared models (4005-EN, 4010-EN, 4020-EN) of Steripath® Micro Blood Collection System (K200661) – utilizes the same technology and principle of operation as the subject device. A comparison of the technological characteristics is listed in Table 5.2.

Table 5.2 Technological Characteristics Comparison

Device Characteristics	Subject Device	Predicate Device	Comparison of subject and Predicate
Intended Use	The Steripath® Micro Blood Collection System is a system to draw blood for *in vitro* diagnostic testing.	The Steripath® Micro Blood Collection System is a system to draw blood for *in vitro* diagnostic testing.	Same
Indication for Use	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 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®).	Same
Materials	Medical grade materials (stainless steel, pvc tubing, medical grade adhesives, polycarbonate, silicone, TPE)	Medical grade materials (stainless steel, pvc tubing, medical grade adhesives, polycarbonate, silicone, TPE)	Same
Inlet Components, User Interface	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set 21G Becton Dickinson Model 367365 (K212724) BD Vacutainer® UltraTouch™ Push Button Blood Collection Set 23G	Luer Extension, 7” ICU Medical, Inc. Model B1754-NS (K964435)	The subject device adds a 9” Luer extension as well as the existing 7” Luer extension. Both Luer extensions are manufactured by ICU Medical and received clearance under K964435. The Patient Interface Components are identical to the predicate device and does not raise new or

Device Characteristics	Subject Device	Predicate Device	Comparison of subject and Predicate
	Becton Dickinson Model 367364 (K212724) Luer Extension, 9” ICU Medical, Inc. Model B1798-NS (K964435) Luer Extension, 7” ICU Medical, Inc. Model B1754-NS (K964435) None (Device provided without inlet component)		different questions of safety or effectiveness. The predicate device, Steripath® Micro Blood Collection System (K200661), has no needle inlet configurations. The needle configurations for the subject device are manufactured using non-sterile BD UltraTouch® needles, which are equivalent to the commercially available BD UltraTouch® Push Button™ Blood Collection Set (K212724), except for the sterilization step. The Steripath® Micro Blood Collection System is validated to SAL^{-6}, with a 25kGy MAX dose and the BD UltraTouch needles (K212724) undergo a single ~25kGy gamma sterilization cycle. This change does not raise new or different questions of safety or effectiveness. The subject device includes no-inlet configurations for compatibility with user supplied venipuncture needles and IV catheters with integrated J-Loops, which are commonly used for blood collection in standard practice. This does not raise new questions of safety or effectiveness.
Outlet Components,	Syringe, 10ml Becton Dickinson	Syringe, 10ml Becton Dickinson	The only difference is the subject device adds

Device Characteristics	Subject Device	Predicate Device	Comparison of subject and Predicate
Culture Bottle Interface	Model 301029 (K980987) Syringe, 20ml Becton Dickinson Model 301031 (K980987) Syringe, 5ml Becton Dickinson Model 301027 (K980987) Transfer Adapter, Maveric Medical Long Neck PN P01045-001 BD Bottle Interface Transfer Adapter, Maveric Medical Wide Neck PN P01042-001 BioMerieux® and ThermoFisher® Bottle interfaces	Model 301029 (K980987) Syringe, 20ml Becton Dickinson Model 301031 (K980987) Syringe, 5ml Becton Dickinson Model 301027 (K980987)	configurations including transfer adapter outlet components. The Maveric Medical Transfer Adapters (TAs) are off-the-shelf components and interact with existing blood culture bottle interface technologies. The changes do not raise any new or different questions of safety or effectiveness.
Diversion Volume	0.5mL to 1.0mL	0.6mL to 0.9mL	Subject Device Average =0.76mL Predicate Device Average =0.75mL Based on these averages, a 1mL reduction in diversion volume raises no new or different questions of safety or effectiveness. Literature supporting Micro diversion volume is referenced in Patton et al.[1]
Mechanism of Diversion	Negative pressure caused by flipping a bladder	Negative pressure caused by flipping a bladder	Same
Mechanism of Sequestering Diversion Sample	Mechanical Isolation	Mechanical Isolation	Same

[1] J Clin Microbiol 2010 Dec;48(12):4501-3 doi: 10.1128/JCM.00910-10. Epub 2010 Oct 13

Device Characteristics	Subject Device	Predicate Device	Comparison of subject and Predicate
User Workflow	+ Access vein + Draw with syringe or bottle + Push button to switch path + Continue to draw with syringe or bottle	+ Access vein + Draw with syringe + Push button to switch path + Continue to draw with syringe	The only difference is the subject device also uses configurations with a transfer adapter outlet, allowing the user to complete blood draw with a culture bottle. This technique is commonly used for blood collection in standard practice and does not raise new or different questions of safety or effectiveness.
Diversion Device Form Factor	4cm Long x 2cm Wide x 4cm High	4cm Long x 2cm Wide x 4cm High	Same
Sterile Packaging	Chevron Pouch, 12” x 6” TPT-0270 to TPF-0524a	Chevron Pouch, 12” x 6” TPT-0270 to TPF-0524a	Same
Shelf Box	E flute Material 15”x5.5”x4.5” 15”x5.5”x7”	E flute Material 15”x5.5”x4.5”	A larger Shelf Box is used for bulkier configurations which incorporate the Wide Neck Transfer Adapters. This larger Shelf Box is made of the same materials as the predicate device Shelf Box and has completed appropriate transportation and conditioning testing per recognized FDA consensus standards. This change does not raise new or different questions of safety or effectiveness.

Device Characteristics	Subject Device	Predicate Device	Comparison of subject and Predicate
Transport Box	Corrugated Kraft material 27.75”x15.25”x14.25” Corrugated Kraft material 28.75”x15.625”x9.625”	Corrugated Kraft material 27.75”x15.25”x14.25”	A larger Transport Box is used for bulkier configurations which incorporate the Wide Neck Transfer Adapters. This larger Transport Box is made of the same materials as the predicate device Transport Box and has completed appropriate transportation and conditioning testing per recognized FDA consensus standards. This change does not raise new or different questions of safety or effectiveness.

5.4. Summary of Performed Testing

The Steripath® Micro Blood Collection System conforms to its System, Labeling, Controls, Interfaces, Accessory, Functional, Physical, Biological Safety and Packaging requirements. As required by the risk analysis, all design verification and validation activities were performed, and the results demonstrated that the predetermined acceptance criteria were met.

a) Sterilization –ISO 11137-1:2006/AMD 2018 “*Sterilization of health care products – Radiation Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices.*”
   - Bacteriostasis/Fungistasis (B/F Test)
   - Bioburden
   - Sterility

   The system complies with the gamma radiation process validated per the VDmax^{SD} 25kGy dose and an SAL of 10^{-6}.

b) Aging/Shelf-Life Test –Prior to distribution, Accelerated Aging is performed in conformity with ASTM F1980-16 “*Standards Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.*”
   - Diversion volume
   - Functional (needle insertion, blood collection, and needle retraction)

- Functional (hub attachment, blood collection, and removal)
- Functional (culture bottle septum puncture, blood collection, and removal)
- Pressure rating
- Protection from harm

The system is validated to a twelve (12) months shelf-life.

c) Biocompatibility testing –ISO 10993-1:2018 "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.* The battery of testing included the following tests:
   - Cytotoxicity
   - Sensitization
   - Irritation (intracutaneous reactivity)
   - Acute System Toxicity
   - Pyrogenicity (LAL)
   - Subacute Toxicity
   - Hemolysis.

   The system meets the requirements for a limited contact duration (≤24 h) or prolonged contact duration (>24 h to 30 d) depending on the device part/component, blood path indirect, contacting device.

d) Packaging Integrity Testing / Shipping Tests –ASTM D4169-16, "*Standard Practice for Performance Testing of Shipping Containers and Systems*", Distribution Cycle 13, Assurance Level II.
   - Seal Strength
   - Package leaks
   - Drop tests

   The system meets the requirements of the standard.

Performance Testing – The Steripath® Micro Blood Collection System successfully meets all functional and performance requirements for safe and effective performance, as noted below. Results of this testing demonstrate that the Steripath® Micro Blood Collection System and its components meet all requirements for its intended use. The performance testing is summarized in Table 5.3.

Table 5.3 Requirements for Safe and Effective Use

Requirement	Description	Verification Test Result
Sequestration	The ISDD® shall sequester the diversion volume.	PASS
Minimum Vacuum performance.	The ISDD® shall meet its performance requirements under minimum vacuum conditions.	PASS
Maximum Vacuum performance.	The ISDD® shall meet its performance requirements under maximum vacuum conditions.	PASS
Diversion Volume.	The ISDD® shall meet the minimum and maximum diversion volume requirements	PASS
Positive Pressure Maximum	The ISDD® shall remain functionally intact and safe under maximum positive pressure conditions	PASS

5.5. Conclusions

The Steripath® Micro Blood Collection System is substantially equivalent to the predicate device - the Steripath® Micro Blood Collection System (K200661) - as it has the same intended use/indications for use. The subject and predicate device function using the same technological characteristics and principles of operation. While there are some differences between the subject and predicate device, the device has been tested appropriately and these differences do not raise new or different questions of safety or effectiveness and the subject device is substantially equivalent to the predicate device.