October 8, 2020

Magnolia Medical Technologies Inc.
Gregory J. Bullington
CEO
200 West Mercer Street, Suite 500
Seattle, Washington 98119

Re: K200661
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: September 10, 2020
Received: September 10, 2020

Dear Gregory J. Bullington:

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 Payal Patel
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200661

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K200661 510(k) Summary

In accordance with 21 CFR 807.92(c) the following summary information is provided:

510(k) Number: K200661

Date Prepared: September 10, 2020

Submitter:

Magnolia Medical Technologies, Inc.
200 West Mercer Street
Suite 500
Seattle WA 98119
Registration number: 3009976527

Contact Person:

Greg Bullington
CEO
Phone: (888) 617-3420
regulatory@magnolia-medical.com

Trade Name: Steripath® Micro Blood Collection System

Common Name: Blood collection set

Regulation Name: Blood Specimen Collection Device

Regulation Number: 862.1675

Regulatory Class: Class II

Product Code: JKA and FPA

Predicate Device: K192247-Steripath® Gen2 Blood Collection System K192247, Reg 862.1675, Product codes JKA & FPA, Class II

Device Description:

The Steripath® Micro Blood Collection System diverts and sequesters the initial portion of the blood specimen (potentially contaminated blood) in the diversion reservoir. When diversion is complete, a subsequent blood sample flows through a second pathway within the device. The subsequent blood sample is collected into a syringe that is used to inoculate culture bottles. Upon removal of the Initial Specimen Diversion Device®, ISDD®, components of the system can be used for infusion per the included manufacturer's instructions for use.

The subject device incorporates multiple syringe oulet accessory configurations that include a luer extension inlet and three sizes of syringes that are previously cleared as referenced below.The following configurations of the Steripath® Micro Blood Collection System are available:

Steripath® Micro Kit Model Number	ISDD®	Inlet Accessory	Outlet Accessory
4005-EN	P00353	Luer Extension, 7" ICU Medical, Inc. Model B1754-NS K964435	Syringe, 5ml Becton Dickinson Model 301027 K980987
4010-EN	P00353	Luer Extension, 7" ICU Medical, Inc. Model B1754-NS K964435	Syringe, 10ml Becton Dickinson Model 301029 K980987
4020-EN	P00353	Luer Extension, 7" ICU Medical, Inc. Model B1754-NS K964435	Syringe, 20ml Becton Dickinson Model 301031 K980987

Table 1: Steripath® Micro Configurations Available

Intended Use/Indications for Use:

The Steripath® Micro Blood Collection System is a system to draw blood for *in vitro* diagnostic testing.

The Steripath® Gen2 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®).

Differences in Intended Use/Indications for Use

The Intended Use / Indications for use are the same as the predicate device except that the Micro device removes the venipuncture needles and associated 2 hour limitation on infusion.

Technology:

The Steripath® Micro Blood Collection System is a single use, sterile, mechanical device that diverts and sequesters the initial 0.6mL to 0.9mL of blood from the patient. The Steripath® Micro is designed for patients where maximum allowable total blood draw volume is limited or for patients with difficult venous access. The system consists of an Initial Specimen Diversion Device® (ISDD®) made of injection molded, medical grade plastics. Off-the-Shelf (OTS) components provide interface to the patient vasculature (via a peripheral IV start not provided by Magnolia) and sample collection is achieve by a syringe. Upon removal of the ISDD®, components of the system can be used for infusion per the included manufacturer's instructions for use.

Differences between the Steripath® Micro Blood Collection System and the Predicate Steripath® Gen2 Blood Collection System are noted in Table 2 below.

Item	Steripath® Micro Blood Collection System K200661	Predicate Device, Steripath® Gen2 Blood Collection System (K192247)	Difference between Steripath® Micro Blood Collection System and Predicate Device
FR Number(s)	862.1675	862.1675	Same
Product Code	JKA and FPA	JKA and FPA	Same
Classification Name	Blood Specimen Collection Device	Blood Specimen Collection Device	Same
Common Name	Blood collection set	Blood collection set	Same
Regulatory Class	Class II	Class II	Same
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
Indications 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®.	The Steripath® Gen2 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®. Venipuncture needles are indicated for short term infusion (less than 2 hours).	Indications for use changed slightly due to removal of venipuncture needles. The changes raise no new questions of safety or effectiveness.
Contraindications	None	None	Same
Prescription Status	Prescription Use Only	Prescription Use Only	Same

Item	Steripath® Micro Blood Collection System	Predicate Device, Steripath® Gen2 Blood Collection System (K192247)	Difference between Steripath® Micro Blood Collection System and Predicate Device
Patient Interface (ISDD® Inlet Accessories)	Luer Extension, 7” ICU Medical, Inc. Model B1754-NS K964435	Blood Collection Set, 21G Becton Dickinson Model 367326 (K030573) Blood Collection Set, 23G Becton Dickinson Model 367324 (K030573) Luer Extension, 9” ICU Medical, Inc. Model B1798-NS (K964435)	Micro adds a 7” Luer extension and removes venipuncture needle patient interfaces. The changes raise no new questions of safety or effectiveness.
Culture Bottle/ Syringe Interface **(ISDD® Outlet Accessories)**	Syringe, 10ml Becton Dickinson Model 301029 (K980987) Syringe, 20ml Becton Dickinson Model 301031 (K980987) Syringe, 5ml Becton Dickinson Model 301027 K980987	Transfer Adapter, BD Luer-Lok Access Device Model 364902 (K991088) BD Bottle Interface Transfer Adapter, Saf-T Holder Blood Culture Device with Male Luer Adapter Smiths Medical Model 96004 & Model 96000S (K081229) BioMerieux® and ThermoFisher® Bottle interfaces Syringe, 10ml Becton Dickinson Model 301029 (K980987) Syringe, 20ml Becton Dickinson Model 301031 (K980987)	Micro adds a 5mL syringe and removes Transfer Adapter bottle interfaces. The changes raise no new questions of safety or effectiveness.
Initial Specimen Diversion Device® (ISDD®)	P00353 Base Assembly, Steripath® Micro	P00133 Base Assembly, Gen2	Average Micro diversion volume = 0.75mL. Average Gen2 diversion volume = 1.75mL. Based on these averages, a 1mL reduction in diversion volume raises no new questions of safety or effectiveness. Literature supporting Micro diversion volume is referenced in Patton et al.[1]
Packaging	Chevron Pouch, 12” x 6” TPT-0270 to TPF-0524a	Chevron Pouch, 12” x 6” TPT-0270 to TPF-0524a	Same
Sterilization Method	Gamma Radiation Steris, Ontario CA	Ethylene Oxide Steris, Temecula CA	The Steripath® Micro gamma radiation sterilization process is validated to FDA recognized consensus standards to the same sterility assurance level as the predicate device (10^{-6}). Therefore this change raises no new

Item	Steripath® Micro Blood Collection System	Predicate Device, Steripath® Gen2 Blood Collection System (K192247)	Difference between Steripath® Micro Blood Collection System and Predicate Device
			questions of safety or effectiveness.
SAL Level	10^{-6}	10^{-6}	Same
Non-pyrogenic	Yes	Yes	Same
Shelf Life	1 year	1 year	Same
Materials	Medical grade materials (pvc tubing, medical grade adhesives, polycarbonate, silicone, TPE)	Medical grade materials (stainless steel, pvc tubing, medical grade adhesives, polycarbonate)	The Steripath® Micro Blood Collection System has slightly different medical grade materials, (thermoplastics, and elastomers) than Steripath® Gen2. Having completed appropriate biocompatibility testing per FDA recognized consensus standards, the changes in materials of the Steripath® Micro of the raise no new questions of safety or effectiveness.
Biocompatibility Testing	ISO 10993-1 ISO 10993-4 ISO 10993-5 ISO 10993-10 ISO 10993-11	ISO 10993-1 ISO 10993-4 ISO 10993-5 ISO 10993-10 ISO 10993-11	The Steripath® Gen2 Blood Collection System was tested in accordance with FDA recognized consensus biocompatibility standards for short duration, blood contacting devices.
Transport Environment	ASTM D4169-09 distribution cycle 13, assurance level II	ASTM D4169-09 distribution cycle 13, assurance level II	Same

Table 2: Substantial Equivalence Table

[1] Patton RG, Schmitt T. (2010) "Innovation for reducing blood culture contamination: initial specimen diversion technique". J. Clin. Microbiol; 48:4501-3

Summary of Performance Testing:

The Steripath® Micro Blood Collection System has been found to conform 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 by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met. It has also been found to conform to FDA consensus, medical device safety and international harmonized standards. Conformity to key medical device safety requirements include:

Sterilization – The system is sterilized using validated Gamma Radiation processes in conformance with ISO 11137-1 "*Sterilization of health care products – Radiation Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*".

Aging/Shelf Life Test – The system is validated to achieve an accelerated 1-year shelf-life. 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*"

Biological Safety (Biocompatibility Tests) – The system meets the requirements of ISO 10993-1:2018 "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*", for a short duration (<24hrs.), blood path indirect, contacting device. Testing included Cytotoxicity, Sensitization, Irritation (intracutaneous reactivity), Acute System Toxicity, Pyrogenicity, and Hemocompatibility.

Packaging Integrity Testing / Shipping Tests – The system meets the requirements of ASTM D4169-16, "*Standard Practice for Performance Testing of Shipping Containers and Systems*", Distribution Cycle 13, Assurance Level II.

Functional and Performance Testing – The system meets its functional requirements for safe and effective performance as noted below.

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

Conclusions: Through performance testing the Steripath® Micro Blood Collection System has demonstrated substantial equivalence to the predicate device, the Steripath® Gen2 Blood Collection System (K192247)