February 28, 2020

Magnolia Medical Technologies, Inc.
John Ray
Director of Operations
200 West Mercer Street
Suite 500
Seattle, Washington 98119

Re: K192247
Trade/Device Name: Steripath Gen2 Blood Collection System
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA, FPA
Dated: January 28, 2020
Received: January 28, 2020

Dear John Ray:

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 Geeta Pamidimukkala
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)*
K192247

Device Name
Steripath® Gen2 Blood Collection System

Indications for Use *(Describe)*
The Steripath® Gen2 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®). Venipuncture needles are indicated for short term infusion (less than 2 hours).

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

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

510(k) Number K192247

Date Prepared: February 28, 2020

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

Contact Person:
John Ray
Director of Operations
Phone: 425-985-8061
john.ray@magnolia-medical.com

Trade Name: Steripath® Gen2 Blood Collection System

Common Name: Blood Collection System

Classification Name: Blood specimen collection device

Regulation Number: 862.1675

Regulatory Class: Class II

Product Code: JKA and FPA

Predicate Device: BD Vacutainer® Push Button Blood Collection Set (K030573)

Device Description: The Steripath® Gen2 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 either directly into a culture bottle (not provided by Magnolia Medical Technologies), or into a syringe that is used to inoculate culture bottles. Upon removal of the ISDD®, components of the system can be used for infusion per the included manufacturer's instructions for use (note: infusion with butterfly needles is limited to less than 2hrs).
The subject device incorporates multiple configurations that include various inlet and outlet accessories that are previously cleared as referenced below.

The following configurations of the Steripath® Gen2 Blood Collection System are available:

Steripath® Kit Model Number	ISDD®	Inlet Accessory	Outlet Accessory
2700-EN	P00133	Luer Extension, 9” ICU Medical, Inc. Model B1798-NS K964435	Transfer Adapter Smith’s Medical Model 96004 K081229
2700-21-EN	P00133	Blood Collection Set, 21G Becton Dickinson Model 367326 K030573	Transfer Adapter Smith’s Medical Model 96004 K081229
2700-23-EN	P00133	Blood Collection Set, 23G Becton Dickinson Model 367324 K030573	Transfer Adapter Smith’s Medical Model 96004 K081229
27BD-EN	P00133	Luer Extension, 9” ICU Medical, Inc. Model B1798-NS K964435	Becton Dickinson Model 364902 K991088
27BD-21-EN	P00133	Blood Collection Set, 21G Becton Dickinson Model 367326 K030573	Becton Dickinson Model 364902 K991088
27BD-23-EN	P00133	Blood Collection Set, 23G Becton Dickinson Model 367324 K030573	Becton Dickinson Model 364902 K991088
27TS-EN	P00133	Luer Extension, 9” ICU Medical, Inc. Model B1798-NS K964435	Transfer Adapter Smith’s Medical Model 96000S K081229
27TS-21-EN	P00133	Blood Collection Set, 21G Becton Dickinson Model 367326 K030573	Transfer Adapter Smith’s Medical Model 96000S K081229
27TS-23-EN	P00133	Blood Collection Set, 23G Becton Dickinson Model 367324 K030573	Transfer Adapter Smith’s Medical Model 96000S K081229
2710-EN	P00133	Luer Extension, 9” ICU Medical, Inc. Model B1798-NS K964435	Syringe, 10ml Becton Dickinson Model 301029 K980987

Steripath® Kit Model Number	ISDD®	Inlet Accessory	Outlet Accessory
2720-EN	P00133	Luer Extension, 9” ICU Medical Model B1798-NS K964435	Syringe, 20ml Becton Dickinson Model 301031 K980987
2710-21-EN	P00133	Blood Collection Set, 21G Becton Dickinson Model 367326 K030573	Syringe, 10ml Becton Dickinson Model 301029 K980987
2720-21-EN	P00133	Blood Collection Set, 21G Becton Dickinson Model 367326 K030573	Syringe, 20ml Becton Dickinson Model 301031 K980987
2710-23-EN	P00133	Blood Collection Set, 23G Becton Dickinson Model 367324 K030573	Syringe, 10ml Becton Dickinson Model 301029 K980987
2720-23-EN	P00133	Blood Collection Set, 23G Becton Dickinson Model 367324 K030573	Syringe, 20ml Becton Dickinson Model 301031 K980987

Table 5-1 Steripath Configurations

Intended Use / Indications for Use

Intended Use/Indications for Use:

The Steripath® Gen2 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®). Venipuncture needles are indicated for short term infusion (less than 2 hours).

Differences in Intended Use/Indications for Use

The predicate device is the same component used in the configurations of the Steripath® Gen2 Blood Collection System. Both the subject device and predicate are intended to draw blood for *in vitro* diagnostic testing.

Both the Steripath® Gen2 Blood Collection System and the predicate device facilitate the collection of blood samples for a variety of *in vitro* diagnostic tests including collection of blood culture samples. Diversion and sequestration of 1.5mL to 2.0mL of the initial sample does not alter this intended use or the indications for use as compared to the predicate.

Diversion and sequestration of 1.5mL to 2.0mL of the initial sample does not raise new questions of safety or effectiveness in the indication of blood collection.

Technology:

The Steripath® Gen2 Blood Collection System is a single use, sterile, mechanical device that diverts and sequesters the initial 1.5mL to 2.0mL of blood from the patient. The system consists of an Initial Specimen Diversion Device® (ISDD®) made of injection molded, medical grade plastics. Off-the-Shelf (OTS) components provide the interface to the patient vasculature, and to the culture bottle or syringe for subsequent sample collection. Upon removal of the ISDD®, components of the system can be used for infusion per the included manufacturer's instructions for use (note: infusion with butterfly needles is limited to less than 2hrs).

The predicate device is also a single use, sterile, mechanical device for collecting blood specimens and is indicated for infusion. The Steripath® Gen2 Blood Collection System includes specimen diversion technology, while the predicate device does not. Inclusion of this technology does not raise new questions of safety or effectiveness.

Differences between the Steripath Gen2 Blood Collection System and the Predicate Device are noted in Table 5-2 below.

Item	Steripath® Gen2 Blood Collection System	Predicate Device, BD Vacutainer® Push Button Blood Collection Set (K030573)	Difference between Steripath® Gen2 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	Tubes, Vials, Systems, Serum Separators, Blood Collection	Tubes, Vials, Systems, Serum Separators, Blood Collection	Same
Common Name	Blood collection set	Blood collection set	Same
Regulatory Class	Class II	Class II	Same
Classification Panel	Clinical Chemistry and Clinical Toxicology Panel, Division of Chemistry and Toxicology Devices, Office of *In Vitro* Diagnostics and Radiological Health	Clinical Chemistry and Clinical Toxicology Panel, Division of Chemistry and Toxicology Devices, Office of *In Vitro* Diagnostics and Radiological Health	Same
Intended Use	The Steripath® Gen2 Blood Collection System is a system to draw blood for *in vitro* diagnostic testing.	The BD Vacutainer® Push Button Blood Collection Set is intended for blood collection.	The predicate device is the same component used in the configurations of the Steripath® Gen2 Blood Collection System.

Item	Steripath® Gen2 Blood Collection System	Predicate Device, BD Vacutainer® Push Button Blood Collection Set (K030573)	Difference between Steripath® Gen2 Blood Collection System and Predicate Device
			Configurations. Both are intended to draw blood for *in vitro* diagnostic testing.
Indications for Use	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).	The BD Vacutainer® Push Button Blood Collection Set is a sterile, multiple sample, single use winged blood collection set intended for venipuncture to obtain blood specimens from patients. The BD Vacutainer® Push Button Blood Collection Set is also indicated for the intravenous administration of fluids as indicated in 21 CFR 820.5440. It may be used for any patient population with consideration given to patient size and appropriateness for the solution being infused and duration of therapy. The recommended use of the device is to activate the needle prior to removal from the venipuncture site. The retraction of the intravenous (IV) end of the needle aids in the prevention of accidental needlestick injury.	The predicate device is the same component used in the configurations of the Steripath® Gen2 Blood Collection System. Configurations. Both are intended to draw blood for *in vitro* diagnostic testing. The fact that the predicate device indications for use do not include diversion technology does not raise new questions of safety or effectiveness given that: Both the Steripath® Gen2 Blood Collection System and the predicate device facilitate the collection of blood samples for a variety of *in vitro* diagnostic tests including collection of blood culture

Item	Steripath® Gen2 Blood Collection System	Predicate Device, BD Vacutainer® Push Button Blood Collection Set (K030573)	Difference between Steripath® Gen2 Blood Collection System and Predicate Device
			samples. Diversion and sequestration of 1.5mL to 2.0mL of the initial sample does not alter this intended use or indications for use as compared to the predicate. Diversion and sequestration of 1.5mL to 2.0mL of the initial sample does not raise new questions of safety or effectiveness in the indication of blood collection.
Contraindications	None	None	Same
Prescription Status	Prescription Use Only	Prescription Use Only	Same
Initial Specimen Diversion Device (ISDD®)	P00133 Base Assembly, Gen2	None	The Steripath® Gen2 Blood Collection System includes the Initial Specimen Diversion Device® to divert and sequester the initial blood sample to reduce frequency of blood culture contamination. The predicate device does not include diversion technology
Packaging	Chevron Pouch, 12” x 6” TPT-0270 to TPF-0524a	PETG Co-polyester tray with paper cover	The Steripath® Gen2 Blood

Item	Steripath® Gen2 Blood Collection System	Predicate Device, BD Vacutainer® Push Button Blood Collection Set (K030573)	Difference between Steripath® Gen2 Blood Collection System and Predicate Device
			Collection System uses a medical grade pouch for the sterile packaging instead of a tray system. Having passed testing per FDA recognized consensus standards for packaging, these differences raise no new questions of safety or effectiveness.
Sterilization Method	Ethylene Oxide Steris, Temecula CA	Gamma Radiation Site unknown	The Steripath® Gen2 Blood Collection System uses a different method of sterilization than the predicate device. Because the Sterility Assurance Level (SAL) is unchanged (10^{-6}), and the process is validated per FDA recognized consensus standards, the sterilization method change raises no new questions of safety or effectiveness.
SAL Level	10^{-6}	10^{-6}	Same

Item	Steripath® Gen2 Blood Collection System	Predicate Device, BD Vacutainer® Push Button Blood Collection Set (K030573)	Difference between Steripath® Gen2 Blood Collection System and Predicate Device
Non-pyrogenic	Yes	Yes	Same
Shelf Life	1 year	2 years	The Steripath® Gen2 Blood Collection System has a shorter shelf-life than the predicate device. Because the Steripath® Gen2 Blood Collection System meets its requirements following real-time aging test, this difference raises no new questions of safety or effectiveness.
Materials	Medical grade materials (stainless steel, pvc tubing, medical grade adhesives polycarbonate)	Medical grade materials (stainless steel needles, pvc tubing, medical grade adhesives)	The Steripath® Gen2 Blood Collection System has the additional medical grade materials, (thermoplastics, and elastomers) contained in the Initial Specimen Diversion Device® (ISDD®). Having completed appropriate biocompatibility testing per FDA recognized consensus standards, the addition of the ISDD® materials

Item	Steripath® Gen2 Blood Collection System	Predicate Device, BD Vacutainer® Push Button Blood Collection Set (K030573)	Difference between Steripath® Gen2 Blood Collection System and Predicate Device
			raises 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	The Steripath® Gen2 Blood Collection System was tested in accordance with FDA recognized consensus biocompatibility standards for short duration, blood contacting devices. Having completed appropriate biocompatibility testing per FDA recognized consensus standards, the addition of the ISDD® materials raises no new questions of safety or effectiveness.
Transport Environment	ASTM D4169-09 distribution cycle 13, assurance level II	Unknown	The Steripath® Gen2 Blood Collection System was tested for transport environment as noted. Having passed testing per FDA recognized consensus standards for transportation

Item	Steripath® Gen2 Blood Collection System	Predicate Device, BD Vacutainer® Push Button Blood Collection Set (K030573)	Difference between Steripath® Gen2 Blood Collection System and Predicate Device
			environment, the test differences raise no new questions of safety or effectiveness.

Table 5-2 Predicate Device Comparison Table

Summary of Performance Testing:

The Steripath® Gen2 Blood Collection System has been found to conform to its System, Labeling, Controls, Interfaces, Accessory, Functional, Physical, Biological Safety and Packaging requirements. 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 Ethylene Oxide (EO) processes in conformance with ANSI/AAMI/ISO 11135:2014 "*Sterilization of Health Care Products-Ethylene Oxide- Requirements for development, validation, and routine control of sterilization process for medical devices*".

Aging/Shelf Life Test – The system is validated to achieve a real-time 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 ANSI/AAMI/ISO 10993-1:2009/(R)2013 "*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, 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.

Because the commercially available predicate device is an accessory to the Steripath® Gen2 Blood Collection System, it was included in tests that were determined to have potential for impact on the predicate device's ability to safely meets its cleared intended use as a blood collection device.

Requirement	Description	Verification Test Result
Unidirectional movement	Operation of the ISDD® actuator shall result in unidirectional movement.	PASS
Backflow prevention	The ISDD® shall not be operable in a manner that allows blood towards patient.	PASS

Requirement	Description	Verification Test Result
Diversion state negative pressure	In the diversion state, the ISDD® shall generate negative pressure in the diversion chamber and inlet flow path	PASS
Minimum diversion volume	The ISDD® shall meet the minimum diversion volume requirement.	PASS
Diversion compliance	The ISDD shall sequester the diversion volume prior to opening the second sample path.	PASS
Fully actuated blood collection	When fully actuated the ISDD shall allow flow through the second sample path.	PASS
Actuation Lock	When fully actuated, the ISDD® shall lock-out travel of the actuator.	PASS
Actuation force, maximum	The ISDD® shall require less than the maximum force to actuate.	PASS
Actuation, blocked inlet	With the inlet blocked, the ISDD® shall remain safe during operation.	PASS
Winged needle accessory	The Steripath® Gen2 Blood Collection System shall be supplied with commercially available, sharps-safe, winged, hypodermic needle assembly.	PASS

Table 5- 3 Key Functional and Performance Requirements

Summary of Clinical Testing

Human studies of the use of the Steripath® Blood Collection System are summarized below. Steripath® results are compared to blood cultures collected using standard procedure without manual diversion.

Investigator	Institution	Total Samples Collected	Samples Collected Using Steripath®	Reduction in Contamination % Using Steripath®
Steripath® Studies Comparing Steripath® to standard blood culture procedure draws (without manual diversion)				
Rupp[1] (company sponsored study)	U. of Nebraska Medical Center (UNMC)	1,808	904	87.6%
Bell[2]	Lee Health	41,685	6,293	82.8%

Table 5- 4 Clinical Testing

Conclusions:

The Steripath® Gen2 Blood Collection System is substantially equivalent to the predicate device, the BD Vacutainer® Push Button Blood Collection Set (K030573).

[1] Rupp ME, et al., *Reduction in Blood Culture Contamination Through Use of Initial Specimen Diversion Device®*, Clinical Infection Diseases, July 2017.

[2] Bell M, et al., *Effectiveness Of A Novel Specimen Collection System In Reducing Blood Culture Contamination Rates*, J Emergency Nursing, November 2018.