October 26, 2022

Eclipse Medcorp LLC
Julie Summerville
Sr. Director of Product Management
5916 Stone Creek Drive Suite #120
The Colony, Texas 75056

Re: K213690
Trade/Device Name: Eclipse Blood Collection Set
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: September 27, 2022
Received: September 27, 2022

Dear Julie Summerville:

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 and Part 809); 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 Payal Patel
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213690

Device Name
Eclipse Blood Collection Set

Indications for Use *(Describe)*

The Eclipse Blood Collection Set with holder is intended to be used with vacuum blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.

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.

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This 510K Summary of safety and effectiveness for the Eclipse Blood Collection Set is submitted in accordance with the requirements of the SMDA 1990, 21 CFR 807.92(c) and following guidance concerning the organization and content of a 510K summary.

Applicant:	Eclipse MedCorp, LLC
Address:	5916 Stone Creek Drive Suite 120 The Colony, TX 75056 USA
Establishment Number:	3009032449
Contact Person:	Julie Summerville
Telephone: **Email:**	972-380-2911 jsummerville@eclipsemed.com
Preparation Date:	October 26, 2022
Device Trade Name:	Eclipse Blood Collection Set
Common Name:	Blood Collection Serum Separators, Systems, Vials, Tubes
Regulation Name:	Blood specimen collection device
Regulation Number:	21 CFR 862.1675 (Product Code: JKA)
Predicate Device:	K200027 Blood Collection Needle
Reference Device:	K151991 Safelock Disposable Blood Collection Set The reference device is included in this submission to demonstrate compliance to ISO 23908:2011 Sharps injury protection-Requirements and test methods. The sharps safety protection for the Eclipse Blood Collection Set is identical to the Safelock Disposable Blood Collection Set.
Regulatory Class:	Class II Prescription
Device Description:	The Eclipse Blood 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 needle stick injury if manually activated

	after the blood draw. For blood collection, the set also includes a blood collection holder for connection to vacuum-based collection vials
Indications for Use:	The Eclipse Blood Collection Set with holder is intended to be used with vacuum blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.
Performance Testing Support:	The following performance data was provided in support of the substantial equivalence determination:

The Eclipse Blood Collection Set was tested for validation and verification of functions based on risk analysis and the results passed predetermined acceptance criteria.

Biocompatibility:
Biocompatibility was evaluated on the final, finished device per the FDA guidance titled Use of International Standard ISO 10993-1 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" – Guidance for Industry and Food and Drug Administration Staff issued in September 2020 with the following endpoints:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Irritation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2017)
- Material Mediated Pyrogenicity (ISO 10993-11:2017, USP 41 NF 36:2018, <151> Pyrogen Test
- Hemocompatibility (Coagulation, Platelets and Hemolysis) (ISO 10993-4:2017)

Performance Data:
Performance testing was evaluation per the International Standard ISO 80369-7:2016 and ISO 80369-20:2015.

Sterilization and Shelf Life:
Ethylene oxide sterilization per ISO 11135-1:2014, ISO11737-1:2018; ISO 11737-2: 2009; ISO 10993-7:2008. The Sterility Assurance Level (SAL) is 10^{-6}.
Sterilization, Shelf Life/Package Integrity in accordance with the following standards: ASTM-F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices; ASTM-F1886-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection; ASTM-F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials; ANSI/AAMI/ISO 11607-1: 2019, Packaging for Terminally Sterilized Medical Devices Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems; ASTM F2096-11 (2019), Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Leak); Real time aging studies are being conducted ambient conditioned storage temperatures for a period of 730 days (2 years). Upon completion of real time aging, half of

the samples will undergo label inspection for overall adhesions and legibility, and seal strength tests per ASTM F88/F88M-15. The other half of the samples will undergo visual inspection per ASTM F1886-16 and bubble leak testing per ASTM F2096-11.

Clinical Study:
Not applicable

Technological Characteristics and Comparison to the Predicate Device:

	Subject Device: Eclipse Blood Collection Set	**Predicate Device: Safety Blood Collection Needle with/without Holder**	**Comparison**
510(k)	K213690	K200027	N/A
Manufacturer	Eclipse MedCorp, LLC The Colony, TX, U.S.A	Jiangsu Caina Medical Co., Ltd. Jiangsu, China	N/A
Device Class	Class II	Class II	Same
Product Code	JKA	JKA	Same
Regulation Number	21 CFR 862.1675	21 CFR 862.1675	Same
Regulation Name	Blood specimen collection device	Blood specimen collection device	Same
Indications for Use / Intended Use	The Eclipse Blood Collection Set with holder is intended to be used with vacuum blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.	The Safety Blood Collection Needle with/without Holder is intended to be used with vacuum blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury. The Luer access device-holder with preattached multiple sample adapter is a sterile, non-invasive device used to connect devices with male or female luer connectors to blood collection tubes for the collection of blood	Different The Eclipse Blood Collection set does not include the preattached adapter therefore this is excluded from the indication for use for the subject device.

	Subject Device: Eclipse Blood Collection Set	Predicate Device: Safety Blood Collection Needle with/without Holder	Comparison
Intended Users	Rx Only: Licensed healthcare practitioners or individuals directed by practitioners	Rx Only: Licensed healthcare practitioners or individuals directed by practitioners	Same
Needle Gauge for Butterfly Needle	23G	20G – 23G	Different
Needle Length for the Butterfly Needle	19.5mm	25.4mm 31.75mm 38.1mm	Different
Needle Gauge for Tube Holder Needle	21G	18G-27G	Different
Needle Length for Tube Holder Needle	23.8mm with the exposed portion 15mm	23.8mm with the exposed portion 15mm	Same
Tube Holder volume	22ml	22ml	Same
Tube Holder function	Hold tube in place during blood draw	Hold tube in place during blood draw	Same
Adapter	Luer	Luer	Same
Needle Safety Shield	Protective sliding cap	Protective hinge shield	Different but same as reference device
Configuration and Materials	Protective Cover of Butterfly Needle – Polypropylene Rubber Sleeve –Isoprene Rubber Patient Needle Tube – Stainless Steel Tube Holder Needle – Stainless Steel Luer lock Male Hub - MABS Tubing – PVC Safety Shield – Polypropylene	Non-patient Needle Cap – Polypropylene Rubber Sleeve – Case Gather Isoprene Rubber Patient Needle Tube – Stainless Steel Needle Tube – Stainless Steel Luer Lock Male Hub – MABS Tubing – PVC Safety Shield – Polypropylene	Same

	Subject Device: Eclipse Blood Collection Set	Predicate Device: Safety Blood Collection Needle with/without Holder	Comparison
	*Tube Holder – Polypropylene Lubricant – Polydimethylsiloxane *NOTE: for the Eclipse device this is also called the Transfer Device	Tube Holder – Polypropylene Lubricant – Polydimethylsiloxane	
Sterilization Method	Ethylene Oxide (EtO) Gas Sterilization	Ethylene Oxide (EtO) Gas Sterilization	Same
Sterility	Meets the SAL of 10^{-6} per ISO 11135-2014	Meets the SAL of 10^{-6} per ISO 11135-2014	Same
Packaging	Tyvek Pouch	Tyvek Pouch	Same
Use	Single Use	Single Use	Same
Performance	Complies with: ISO 9626 ISO 7864 ISO 80369-7	Complies with: ISO 9626 ISO 7864 ISO 80369-7	Same
Biocompatibility	Tested to ISO 10993	Tested to ISO 10993	Same
Shelf Life	2 years	2 years	Same
Endotoxin Limit	<20 EU per device	<20 EU per device	Same

Discussion of Differences:

Needle gauge for the butterfly needle: The subject device is 23G which is a subset of the dimension for the predicate device, which is 20G – 23G. The subject device has only the 23G needle, but this size is previously cleared in the predicate device, therefore, it presents no new concerns for safety or efficacy. Therefore, the subject device needle gauge is the same as the predicate device. Performance testing was conducted per ISO 9626: 2016 *Stainless Steel Needle tubing for the manufacture of medical devices and ISO 7864:2016 Sterile Hypodermic Needles for Single Use* and verify the proposed device met all design specifications. There are no safety or efficacy concerns related to the use of the 23G needle.

Needle length for butterfly needle: The subject device length is 19.5mm. This is shorter than the lengths for the predicate device. According to peer reviewed published information butterfly needle length is typically between ½ to ¾ inches (12.7mm-19.05mm). This length is desirable because it can be inserted at a shallow angle and is therefore easier to use. The difference between 19.05mm (common size) and the subject device length of 19.50 is 0.45mm (0.017 inches) and is not significant Performance testing was conducted to the FDA consensus

standards and verify the proposed device met all design specifications. The difference in length for the subject device and predicate device does not raise any new safety or efficacy concerns. Performance testing was conducted per ISO 9626: 2016 *Stainless Steel Needle tubing for the manufacture of medical devices and ISO 7864:2016 Sterile Hypodermic Needles for Single Use* and verify the proposed device met all design specifications. There are no safety or efficacy concerns related to the use of the 23G needle

Needle gauge for the needle within the tube holder: The 21G needle for the tube holder is a subset of the cleared sizes for the predicate device. Therefore, the subject device is the same as the predicate device. Performance testing was conducted per ISO 9626: 2016 *Stainless Steel Needle tubing for the manufacture of medical devices and ISO 7864:2016 Sterile Hypodermic Needles for Single Use* and verify the proposed device met all design specifications. There are no safety or efficacy concerns related to the use of the 23G needle

Substantial Equivalence:
The Eclipse Blood Collection Set is substantially equivalent to the Jiangsu Caina Safety Blood Collection Needle with/without Holder predicate device. The devices are under the same product code (JKA) and regulation number, both have the similar intended use/indication for use, similar lengths and gauges of needles, same materials, packaging and sterilization method. The only technological differences are the indications for use are the same with one exception. The Eclipse Blood Collection Set does not include a pre-attached adapter. Therefore, the following indication for use is not included: “The luer access device- holder with pre-attached multiple sample adapter is sterile, non-invasive device used to connect devices with male or female luer connectors to blood collection tubes for the collection of blood.” The needle gauge is identical to the predicate, although both the butterfly needle and needle within the tube holder differ in length between the proposed device and the predicate device; however, this difference is just in dimension. The difference in lengths is minor and does not raise new issues of safety or effectiveness and performance testing demonstrates the subject device can perform its intended function.

Conclusion:
The Eclipse Blood Collection Set is considered to be substantially equivalent to the predicate device based on the intended use, technological characteristics, and the results of device testing submitted.