November 5, 2020

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

Re: K200017
Trade/Device Name: Eclipse DermaFlex Cannula
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: October 1, 2020
Received: October 5, 2020

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); 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 CAPT Alan Stevens
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)*

K200017

Device Name
Eclipse DermaFlex Cannula

Indications for Use *(Describe)*
The Eclipse DermaFlex Cannula is intended to inject fluids intradermally.

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."

510(K) Summary-
K200017
Prepared: June 30, 2020

1. **510k Submitter**
Eclipse MedCorp, LLC.
5916 Stone Creek Dr. Suite #120
The Colony, TX 75056 U.S.A.
Tel: (972) 380-2911
Fax: (866) 558-0415

2. **Contact Person**
Julie Summerville
Sr. Dir. of Product Management
Eclipse MedCorp, LLC
972.380.2911 x2405
jsummerville@eclipsemed.com

3. **Device Name:**
   - Trade Name : Eclipse DermaFlex Cannula
   - Regulation Description: Hypodermic single lumen needle
   - Device Class: Class II
   - Product Code: FMI
   - Regulation Number: 21 CFR Part 880.5570
   - Review Panel: General Hospital

4. **Predicate Device:**
MV INTRADERMIC NEEDLES; MAGIC NEEDLE (K110606) by M.V. S.R.L.

5. **Device Description:**
The Eclipse DermaFlex Cannula is provided as a single-use, sterile device. It is comprised of a needle, hub and cap. This device comes in a variety of needle gauges and lengths. The Eclipse DermaFlex Cannula offers AN type and B Type. The AN type is a hypodermic single lumen needle intended to prepare the site for injection. The tip of this pilot needle is sharpened at one end, while the other end is joined to a hub. The B type has a metal tube with the tip, which is closed and blunt, while the cannula has an opening laterally at a lower point under the tip. On the other end, the device is joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe or secondary medication sets to prepare and administer fluids/ medications/ drugs to a patient.

6. **Indication:**
The Eclipse DermaFlex Cannula is intended to inject fluids intradermally.

7. **Technological Characteristics:**
The subject device has the same indications for use, principle of operation and structure. The subject device is comprised of the same materials as the predicate, offers the same range of needle gauges and has the same syringe connection type. The needle tube length of the subject device, DermaFlex Cannula is within the size range of the predicate device. The subject device is marketed with a blunt tip needle and pilot needle. The predicate device is marketed with blunt tip needle and with or without a hypodermic needle (pilot needle).; however, both perform the same intended use. Additionally, there are slight differences in the design of the needle and cannula tips between the subject and predicate devices. The inclusion of the hypodermic needle and the slight differences in design are not considered to raise new questions of safety and effectiveness. Further, successful testing of the subject device to appropriate performance testing has been performed and these differences does not raise new questions with regard to safety and effectiveness.

Table of Technological Characteristics			
	Subject Device	**Predicate Device**	**Comments**
Device Name	Eclipse DermaFlex Cannula	MV INTRADERMIC NEEDLES; MAGIC NEEDLE; MAGIC NEEDLE	NA
510k Applicant	Eclipse MedCorp, LLC.	M.V. S.R.L.	NA
Product Code	FMI	FMI	Same
510k Number	K200017	K110606	NA
Indications for Use	The Eclipse DermaFlex Cannula is intended to inject fluids intradermally.	The MV intradermic needles are intended to inject fluids intradermally.	Same
Structure	Hub, Needle, Protective Cap	Hub, Needle, Protective Cap	Same
Principle of Operation	This device is used in conjunction with a piston syringe to deliver fluids/ medications/drugs into the body. The device consists of a metal tube (needle), joined to a female connector (hub). This device comes in a variety of needle gauges and lengths.	This device is used in conjunction with a piston syringe to deliver fluids/ medications/drugs into the body. This device consists of metal tube (needle), joined to a female connector (hub). This device comes in a variety of needle gauges and lengths.	Same
Tip Configuration	Sharpened tip (pilot needle) Closed blunt tip, lateral opening (Intradermic needle)	Sharpened tip (pilot needle Closed blunt tip, lateral opening (Intradermic needle)	Same
Needle Gauge	21, 22, 23, 25, 26, 27, 30	21, 22, 23, 25, 26, 27, 30	Same
Needle Tube Length	25, 38, 40, 50, 60, 70mm	13, 25, 27, 35, 37, 40, 50, 57, 70mm	Equivalent: Needle lengths within predicate's range
Needle Tube Material	Stainless Steel 304	Stainless Steel 304	Same
Connection to Syringe	Luer taper	Luer taper	Same
Needle Hub Material	Polypropylene	Polypropylene	Same
Needle Cap Material	Polypropylene	Polypropylene	NA
Lubricant Composition	Silicone	Silicone	Same
Sterilization method	Ethylene Oxide Gas	Ethylene Oxide Gas	Same

Performance Testing
Performance testing for the DermaFlex Cannula was conducted in accordance with the following standards.

- Sterilization Validation Test in accordance with ISO 11135, ISO 11138-1, ISO 11138-2, ISO 11737-1, ISO 10993-7, and AAMI TIR28
- Shelf Life Validation Test in accordance with ISO 11608-2, ASTM F1929, and ISO 11737-2
- Biocompatibility testing in accordance with ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993- 11, ISO 10993-4
- Performance Tests in accordance with ISO 9626:2016, ISO 7864: 2016, ISO 80369-7
- ISO 6009: 2016–Hypodermic needles for single use – Colour coding for identification

The results of the performance testing for the device type demonstrate the device meets the established characteristics and performance requirements needed to perform its intended function. Substantial equivalence is established as these are the same standards established for the predicate device as well. As the Eclipse meets the required criteria of the standards, its performance may be considered to support substantial equivalence**.**

Conclusion
Based on the information provided in this premarket notification, Eclipse MedCorp, LLC concludes that the Eclipse DermaFlex Cannula is substantially equivalent to predicate device.