November 24, 2021

Eclipse Medcorp LLC
Julie Summerville
Senior Director of Product Management
5916 Stone Creek Drive
The Colony, Texas 75056

Re: K212558
Trade/Device Name: MicroPen EVO
Regulation Number: 21 CFR 878.4430
Regulation Name: Microneedling Device For Aesthetic Use
Regulatory Class: Class II
Product Code: QAI
Dated: September 1, 2021
Received: September 2, 2021

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 Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K212558

Device Name

MicroPen® EVO

Indications for Use *(Describe)*

The Eclipse MicroPen® EVO is a microneedling device and accessories intended to be used as a treatment to improve the appearance of wrinkles of the neck for Fitzpatrick skin types II - IV and to improve the appearance of facial acne scars in adults with all Fitzpatrick skin types aged 22 years and older.

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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510(k) Summary [This 510(k) Summary is submitted in accordance with 21 CFR Part 807.92(c)]				
Submitted by:	Eclipse Medcorp, LLC. 5916 Stone Creek Dr. Suite 120 The Colony, TX 75056	**Contact Person:**	Julie Summerville Senior Dir of Product Management972-380-2911 x 2405 jsummerville@eclipsemed.com	
Date Prepared:	November 3, 2021			
Trade Name:	MicroPen EVO™			
Common Name:	Powered Microneedling Device			
Product Code; Regulation Name & No:	QAI	Microneedling device for aesthetic use		21 CFR §878.4430

Device Description:

The Eclipse MicroPen EVO™ is a minimally invasive microneedling device that mechanically creates microscopic punctures in the epidermal layers of the skin by means of micro-needles in a reciprocating cartridge head. The MicroPen EVO is comprised of a reusable pen body, a sterile, single use microneedlingcartridge, a rechargeable battery pack, and a battery charger with power supply. The microneedling cartridge is attached to the pen body and activated with an On/Off button. The depth of needle penetrationcan be adjusted by the user depending on the condition of the skin being treated. Charging is accomplished by placing the MicroPen EVO battery pack on the Charger base.

Indications for Use:

The Eclipse MicroPen® EVO is a microneedling device and accessories intended to be used as a treatment to improve the appearance of wrinkles of the neck for Fitzpatrick skin types II - IV and to improve the appearance of facial acne scars in adults with all Fitzpatrick skin types aged 22 years and older.

Predicate Device:

The Eclipse MicroPen EVO predicate device is the SkinPen Precision System by Crown Aesthetics (formerly Bellus Medical), K202243.

Reference Device:

The Eclipse MicroPen EVO K203144 is a reference device for the Eclipse MicroPen EVO that is subject to this submission.

Technological Characteristics and Comparison to Predicate:

Technological Characteristics Comparison Chart			
	Subject device Eclipse MicroPen EVO	**Predicate SkinPen Precision System**	**Comparison**
510(k)	K212558	K202243	NA
Manufacturer	Eclipse MedCorp LLC	Crown Aesthetics	NA
Trade Name	MicroPen EVO™	SkinPen® Precision System	NA
Product Code	QAI	QAI	Same
Regulation #	21 CFR Part 878.4430	21 CFR Part 878.4430	Same
Reg Name	Microneedling device for aesthetic use	Microneedling device for aesthetic use	Same
Device Class	Class II	Class II	Same
Indication for use / Intended use	The Eclipse MicroPen® EVO is a microneedling device and accessories intended to be used as a treatment to improve the appearance of wrinkles of the neck for Fitzpatrick skin types II - IV and to improve the appearance of facial acne scars in adults with all Fitzpatrick skin types aged 22 years and older.	The SkinPen Precision System is a microneedling device and accessories intended to be used as a treatment to improve the appearance of wrinkles of the neck for Fitzpatrick skin types II - IV and to improve the appearance of facial acne scars in adults with all Fitzpatrick skin types aged 22 years and older.	Same
Intended Users	Rx Only: Licensed healthcare practitioners or individuals directedby practitioners	Rx Only: licensed healthcare practitioners or individuals directedby practitioners	Same
Use Location	Face	Face	Same
Power Source (Pen Body)	Rechargeable Li-ion battery	Rechargeable Li-ion battery	Same
Power Source (Battery Charger)	AC Powered	AC Powered	Same
Control Mechanism	Microprocessor; embedded software	Microprocessor; embedded software	Same
Control Mechanism	Microprocessor; embedded software	Microprocessor; embedded software	Same
Operating Principle	Rotary	Rotary	Same
Single Speed(RPM)	6300-7700	6300 - 7700	Same

Puncture Rate	105-128 stamps/second	105 -128 stamps/second	Same
Microneedling Cartridge	Sterile, Single Use	Sterile, Single Use	Same
No. of Needles	14	14	Same
Needle Gauge	32 Ga	32 Ga	Same
Needle Material	Stainless Steel	Stainless Steel	Same
Needle Shape Geometry	Straight, cylindrical body with a conical tapered, sharp point	Straight, cylindrical body with aconical tapered, sharp point	Same
Arrangement	Needles radially arranged	Needles radially arranged	Same
Needle Spacing	2 mm spacing/3.48 mm^2 per needle	2 mm spacing/3.54 mm^2 per needle	Equivalent: subject device has a slightly smaller total surface area of the hub. No affect to geometry, puncture pattern, needle stamp.
Penetration Depth	1.5 mm (Recommended)	1.5 mm (Recommended)	Same
Max Needle Depth Setting	2.25 mm	2.5 mm	Different: Not significant; treatment depth is 1.5 mm for both devices.
Penetration Depth Selection	9 depth settings; 0 mm to 2.0 mm in 0.25 mm increments	11 depth settings; 0 mm to 2.5mm in 0.25 mm increments	Similar
Sterility (cartridge)	Ethylene Oxide	Ethylene Oxide	Same
Shelf Life (Cartridge)	2 years	2 years (min)	Same
Barrier: Cross-Contamination	MicroSleeve Sheath(Disposable)	BioSheath (Disposable)	Same

Performance Data:
In combination with the general controls of the FD&C Act, the Eclipse MicroPen EVO™ microneedling device for aesthetic use has been subjected to performance testing and adheres to the following special controls and standards:

- Puncture rate; needle penetration depth and accuracy; needle retention; battery life; use life; cartridge reliability, and suction prevention testing;
- Fluid ingress testing for cross contamination prevention;
- Cleaning and disinfection validation for reusable components;
- Biocompatibility evaluation conducted in accordance with ISO 10993-1 on the final, finished microneedling cartridge: (1) Cytotoxicity (ISO 10993-5:2009); (2) Sensitization and (3) Irritation/Intracutaneous Reactivity (ISO 10993-10: 2010); (4) Acute Systemic Toxicity (ISO 10993-11:2017); (5) Material Mediated Pyrogenicity (ISO 10993-11:2017, USP 41 NF 36:2018, <151> Pyrogen Test. The results of these tests demonstrated the device to be biocompatible with no evidence of material mediated pyrogenicity.
- Sterilization, Shelf Life/Package Integrity in accordance with the following standards:
  - Ethylene oxide sterilization per ISO 11135-2014; ISO11737-1:2018; ISO 11737-2: 2009; ISO 10993-7:2008
  - ASTM-F1980 Std Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
  - ASTM-F1886-2016 Std Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection;
  - ASTM-F1929-2015 Std Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
  - ASTM-F88 Std Test Method for Seal Strength of Flexible Barrier Materials; ANSI/AAMI/ISO 11607-1: 2006(R) 2010/ A1-2014, Packaging for Terminally Sterilized Medical Devices Part 1: Requirements for Materials, Sterile Barrier System and Packaging Systems
- Electrical Safety and Electromagnetic Compatibility: IEC- 60601-1:2005 + A1: 2012 – Medical electrical equipment– Part 1: General Requirements for Basic Safety and Essential Performance
- EN/IEC 60601-1-2: 2015 /IEC 60601-1-2:2014–Medical electrical equipment–Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirement and tests

Substantial Equivalence:
The MicroPen EVO is substantially equivalent to the Crown Aesthetics SkinPen® Precision System predicate device. The devices are under the same product code (QAI), both have the same intended use/ indication for use, same number of needles, gauge, shape and arrangement, same material, recommended penetration depth, speed, puncture rate and sterilization method. The only technological differencesare the maximum needle depth setting: the MicroPen EVO is 0.5 mm shorter (2.0 mm) than the predicate (2.5 mm); and the penetration depth selection: the MicroPen EVO has 9 depth settings (0-2.0 mm in 0.25 mm increments) and the predicate device has 11 depth settings (0-2.5 mm in 0.25 mm increments). These differencesare minor and are not significant since both devices recommend the same treatment depth (1.5 mm).

There is a small and insignificant difference between the subject and predicate in total surface area of the hub, however theneedle spacing is the same (2 mm) and there is no effect on geometry, puncture pattern, needle stamp. These minor differences do not raise new questions of safety and effectiveness. Further, the results of performance testing support substantial equivalence of the Eclipse MicroPen EVO to the predicate device and demonstrate the MicroPen EVO can perform its intended function.

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