August 11, 2023

Guangzhou Ekai Electronic Technology Co., Ltd.
% Helen Nan
General Manager
New Risen Enterprise Management Consulting Co., Ltd.
Room 302, Building 3, Hangqian Mansion
Hangqian Street, Lucheng District
Wenzhou, Zhejiang 325000
China

Re: K230420
Trade/Device Name: Dr. pen Microneedling System
Regulation Number: 21 CFR 878.4430
Regulation Name: Microneedling Device For Aesthetic Use
Regulatory Class: Class II
Product Code: QAI
Dated: July 14, 2023
Received: July 14, 2023

Dear Helen Nan:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.08.11 08:02:17 -04'00'

Mark Trumbore, 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)*
K230420

Device Name
Dr.pen Microneedling System

Indications for Use *(Describe)*
The Dr.pen Microneedling System is a microneedling device and accessories intended to be used as a treatment to improve the appearance of facial acne scars in adults 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.

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."

广州意凯电子科技有限公司
Guangzhou Ekai Electronic Technology Co., Ltd.

K230420_510(k) Summary
(As required by 21 CFR 807.92(a))

1.0 Submitter Information

Company:	Guangzhou Ekai Electronic Technology Co.,Ltd.
Address:	Third Floor, Building E, No.81 Zijing Road, Liwan District, Guangzhou, Guangdong, CHINA
Phone:	+86-20-81177539
Contact Person:	Guihua Chen
Title:	CEO

Summary Prepared Date: July 14th, 2023

2.0 Device Information

Trade/Device Name:	Dr.pen Microneedling System
Model:	A20
Device:	Powered Microneedle Device
Regulation Description:	Microneedling device for aesthetic use.
Product Code:	QAI
Review Panel:	General & Plastic Surgery
Submission Type:	510(k)
Regulation Number:	CFR 878.4430
Device Class:	Class II

3.0 Predicate Device and Reference Device Information

Predicate Device:

Trade/Device Name:	SkinPen® Precision System
K Number:	DEN160029
Submitter:	Bellus Medical, LLC

Reference Device:

Trade/Device Name:	MicroPen EVO™
K Number:	K203144
Submitter:	Eclipse MedCorp, LLC

4.0 Device Description

The Dr.pen Microneedling System is a minimally invasive microneedling device that mechanically creates microscopic punctures in the epidermal and dermal layers of the skin by means of micro-needles in a reciprocating cartridge head. The Dr. pen Microneedling System is comprised of a reusable pen body, a sterile, single use microneedling cartridge, a power adapter, and a disposible protective sleeve. The microneedling cartridge is attached to the pen body and activated with an On/Off button. The depth of needle penetration can be adjusted by the user depending on the condition of the skin being treated. Charging is accomplished by attaching the Dr.pen pen body to the power adapter.

5.0 Indications for Use

The Dr.pen Microneedling System is a microneedling device and accessories intended to be used as a treatment to improve the appearance of facial acne scars in adults aged 22 years and older.

广州意凯电子科技有限公司
Guangzhou Ekai Electronic Technology Co., Ltd.

6.0 Comparison of Technological Characteristics with the Predicate Device

The Dr.pen Microneedling System has the identical intended use and indications for use as the predicate device and the same or equivalent technological features. A comparison of the subject and predicate device's technological features is presented in the following table.

Property	Predicate Device	Reference Device	Subject Device	Comparison
Device Name	SkinPen® Precision System	MicroPen EVO™	Dr.pen Microneedling System	-
510(K) Number	DEN160029	K203144	K230420	-
Classification name	Microneedling device for aesthetic use	Microneedling device for aesthetic use	Microneedling device for aesthetic use	Same
Product Code	QAI	QAI	QAI	Same
Classification	Class II	Class II	Class II	Same
Regulation Number	21 CFR 878.4430	21 CFR 878.4430	21 CFR 878.4430	Same
Use	Prescription use	Prescription use	Prescription use	Same
Indications For Use	SkinPen® Precision System is a microneedling device and accessories intended to be used as a treatment to improve the appearance of facial acne scars in adults aged 22 years or older.	The Eclipse MicroPen EVO is a microneedling device and accessories intended to be used as a treatment to improve the appearance of facial acne scars in adults aged 22 years and older.	The Dr.pen Microneedling System is a microneedling device and accessories intended to be used as a treatment to improve the appearance of facial acne scars in adults aged 22 years or older.	Same
Intended Location of Use	Face	Face	Face	Same
Power Source (Pen Body)	Rechargeable Li-ion battery	Rechargeable Li-ion battery	Rechargeable Li-ion battery	Same
Power Source (Battery Charger)	AC Powered	AC Powered	AC Powered	Same

广州意凯电子科技有限公司
Guangzhou Ekai Electronic Technology Co., Ltd.

Control Mechanism	Microprocessor; embedded software	Microprocessor; embedded software	Microprocessor; embedded software	Same
Single Speed (RPM)	6300 - 7700	6300 - 7700	6300 - 7700	Same
Puncture Rate	105 -128 stamps/second	105 -128 stamps/second	105 -128 stamps/second	Same
Microneedling Cartridge	Sterile, Single Use	Sterile, Single Use	Sterile, Single Use	Same
No. of Needles	14	14	14	Same
Needle Gauge	34 Ga	34 Ga	34 Ga	Same
Needle Material	Stainless Steel	Stainless Steel	Stainless Steel	Same
Needle Shape Geometry	Straight, cylindrical body with a conical tapered, sharp point	Straight, cylindrical body with a conical tapered, sharp point	Straight, cylindrical body with a conical tapered, sharp point	Same
Arrangement	Needles radially arranged	Needles radially arranged	Needles radially arranged	Discussion[1]
Needle Spacing	2 mm spacing/3.54 mm^2 per needle	2 mm spacing/3.48 mm^2 per needle	2 mm spacing/3.96 mm^2 per needle	Discussion[2]
Penetration Depth	1.5 mm (Recommended)	1.5 mm (Recommended)	1.5 mm (Recommended)	Same
Max. Needle Depth Setting	2.5 mm	2.00 mm	2.0 mm	Discussion[3]
Penetration Depth Selection	11 depth settings; 0 mm to 2.5 mm in 0.25 mm increments	9 depth settings; 0 mm to 2.0 mm in 0.25 mm increments	9 depth settings; 0 mm to 2.0 mm in 0.25 mm increments	
Sterility (cartridge)	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Same
Shelf Life (cartridge)	2 years	2 years	2 years	Same
Barrier: Cross/ Contamination	BioSheath (Disposable)	MicroSleeve Sheath (Disposable)	Protective Sleeve (Disposable)	Same

Discussion[1]: the reference device (Eclipse MicroPen EVO, K203114) has included to support that the needle arrangement of the subject device is the same as the reference device and state substantial equivalence to the a legally marketed device.

Discussion[2]: subject device has a slightly larger total surface area of the hub. No affect to geometry, puncture pattern, needle stamp.

Discussion[3]: not significant difference; treatment depth is 1.5 mm for both devices.

Substantial Equivalence:
Dr.pen Microneedling System is substantially equivalent to the Bellus Medical 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 differences are the maximum needle depth setting: the Dr.pen is 0.5 mm shorter (2.0 mm) than the predicate (2.5 mm); and the penetration depth selection: the Dr.pen 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 differences are 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 the needle spacing is the same (2 mm) and there is no effect on geometry, puncture pattern, needle stamp. These minor differences do not raise different questions of safety and effectiveness. Further, the results of performance testing support substantial equivalence of the Dr.pen Microneedling System to the predicate device.

7.0 Performance Testing-Bench

In combination with the general controls of the FD&C Act, the Dr.pen Microneedling System for aesthetic use has been subjected to performance testing and adheres to the following special controls and standards:

7.1 Bench Testing

- Motor Speed Puncture Rate Testing
- Needle Penetration Depth and Extension Accuracy Testing
- Needle Bonding Strength Test
- Use Life Testing
- Cartridge Life Testing
- Anti-suction Testing
- Microbial Ingress Testing

7.2 Cleaning and Disinfection Validation

- ISO 11737-1: 2018 (AAMI TIR-30; 2011; AAMI TIR-12:2004) Cleaning Validation Intermediate-Level Disinfection Validation

7.3 Sterilization and Shelf Life

- Ethylene oxide sterilization per ISO 11135-2014; ISO11737-1:2018; ISO 11737-2: 2009; ISO 10993-7:2008
- Sterilization, Shelf Life/Package Integrity in accordance with the following standards:
  - Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices medical devices ASTMF1980-16
  - Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection ASTM F1886/F1886M-16
  - Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration ASTM F1929-2015
  - Standard Test Method for Stripping Strength of Flexible Sealing Materials ASTM F88/F88M-2015
  - Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission ASTM D3078-02(2013)
  - Standard Test Methods For Internal Pressurization Failure Resistance Of Unrestrained Packages ASTM F1140-2013
  - Sterilization - Sterile supply - Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized DIN 58953-6:2016
  - Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process ISO 11737-2: 2019

8.0 Biocompatibility

The following tests were performed on the final, finished microneedling cartridge:

- Cytotoxicity (ISO 10993-5:2009);

- Sensitization and Irritation/Intracutaneous Reactivity (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).

The results of these tests demonstrated the device to be biocompatible with no evidence of material mediated pyrogenicity.

10.0 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.

11.0 Statement of Substantial Equivalence

The results of the performance testing described above demonstrate that Dr.pen Microneedling System is as safe and effective as SkinPen® Precision System [510K Number: DEN160029; submitted by Bellus Medical, LLC] supports a determination of substantial equivalence.