April 7, 2025

Bomtech Electronics Co., Ltd.
% Seo Juntaek
President
Corazon
20, Jukjeon-ro, Giheung-gu, Gyeonggi-do
Yongin, 16897
Korea, South

Re: K243143
Trade/Device Name: E-pen (e-pen)
Regulation Number: 21 CFR 878.4430
Regulation Name: Microneedling Device For Aesthetic Use
Regulatory Class: Class II
Product Code: QAI
Dated: February 28, 2025
Received: February 28, 2025

Dear Seo Juntaek:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Wilmarie Flores -S

For Tek Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243143

Device Name
E-PEN

Indications for Use *(Describe)*
The E-PEN 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.

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"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

I. Submitter

510(k) Submitter: BOMTECH ELECTRONICS CO., LTD.
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Phone: +82 2 523 8295

Primary Contact: Juntaek Seo
info@corazon.kr

Alternate Contact: Junseok Lee
RA manager
bomtech@bomtech.net

Date prepared: 08, September, 2024

II. Device Name

Device Trade Name	E-PEN
Common Name	Powered Microneedle Device
Regulation Number	21 CFR 878.4430
Regulatory Class	Class II
Product Code	QAI

III. Legally Marketed Predicate Device

Predicate #	DEN160029
Predicate Trade Name	SkinPen Precision System

IV. Device Description

The E-PEN is a 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 E-PEN is comprised of a reusable pen body, a sterile, single use microneedling cartridge, and a power adapter. 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 E-PEN pen body to the power adapter.

V. Indications for Use

The E-PEN 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.

VI. Comparison of technological characteristics with the predicate device

The E-PEN is substantially equivalent to the following predicate device:

Primary Predicates: For Indication for Use and Technological Characteristics:

- DEN160029, SkinPen Precision System

Item	E-PEN	SKINPEN PRECISION SYSTEM	Remark
510(k) Number	-	DEN160029	-
Manufacturer	Bomtech Electronics Co., Ltd.	Bellus Medical, LLC	-
Regulation Number No.	21 CFR 878.4430	21 CFR 878.4430	Same
Product Code	QAI	QAI	Same
Indications for Use	The E-PEN 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.	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.	Same
Prescription or OTC	Prescription	Prescription	Same
Intended Location of Use	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
Single Speed (RPM)	6,300~7,700	6,300~7,700	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	34 G	34 G	Same
Needle material	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	Same
Arrangement	Needles radially arranged	Needles radially arranged	Same

Item	E-PEN	SKINPEN PRECISION SYSTEM	Remark
Needle Spacing	2 mm spacing/3.18 mm^2 per needle	2 mm spacing/3.54 mm^2 per needle	**Similar (Note 1)**
Penetration Depth	1.5 mm (Recommended)	1.5 mm (Recommended)	Same
Max. Needle Depth Setting	2.00 mm	2.5 mm	**Similar (Note 2)**
Sterility (Cartridge)	Ethylene Oxide	Ethylene Oxide	Same

Note 1: **Needle Spacing**
Subject device has a slightly smaller total surface area of the hub. No affect to geometry, puncture pattern, needle stamp.

Note 2: Max. Needle Depth Setting
Not significant difference; treatment depth is 1.5mm for both devices.

E-PEN 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 E-PEN is 0.5 mm shorter (2.0 mm) than the predicate (2.5 mm); 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 E-PEN to the predicate device. Safety and effectiveness for needle depth settings greater than 1.5 mm has not been evaluated. The E-PEN allows for incremental increase in settings of up to 2.5mm to allow for the variability in thickness of healthy skin and acne scar tissue. However, the device has not been clinically evaluated at cartridge settings of greater than 1.5mm. As there are fine structures (i.e., nerve branches and accompanying blood vessels) that run under the skin and are essential to proper tissue function, it is not recommended to treat at needle depths greater than 1.5mm. This precaution can also be found in the "Precautions before use" section of the user manual provided by Bomtech Electronics.

VII. Performance data

1. Biocompatibility Testing

In accordance with ISO 10993-1 the subject device is classified as: Externally Communicating Device, Blood Path Indirect, Limited Contact (<24hours). The following testing was conducted.

1) Cytotoxicity
2) Sensitization
3) Irritation
4) Acute Systemic Toxicity
5) Material Mediated Pyrogenicity

2. Sterilization validation test

To confirm a sterility assurance level of 10^{-6} for EO sterilization, the validation process employed the biological indicator (BI) overkill method, following the guidelines outlined in ISO 11135, ISO 10993-1, ISO 10993-7, ISO 11138-1, ISO 11138-2, ISO 11737-1, ISO 11737-2, ISO 11140-1, AAMI TIR 15, AAAMI TIR 16, and AAMI TIR 28.

3. Sterility, Shipping and Shelf-Life

The sterilization method is Ethylene Oxide. EO- not detected, ECH- Not detected, validation method: Overkill Approach (e.g., Half-Cycle method), pyrogen test: Bacterial endotoxin USP <161>Medical devices -Bacterial Endotoxin and pyrogen test, USP <85> Bacterial endotoxins test.

- Package integrity testing, after environmental conditioning and simulated transportation using ASTM D4169-22, was conducted on final packaged, and sterile devices. All packaging is acceptable for protection of final finished product and sterility maintenance.

- Sterile Barrier Packaging Testing performed on the proposed device:
  - Seal peel test – ASTM F88/F88 -15
  - Dye migration- ASTM F1929-15

- Shelf life of 3 years is validated using the FDA recognized standard ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier System for Medical Devices.

4. EMC & Electrical safety test

1) IEC-60601-1:2005+A1:2012 – Medical electrical equipment–Part 1: General Requirements for Basic Safety and Essential Performance;
2) 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

5. Software validation test

The level of concern of the software of the E-PEN is moderate and the software validation tests were performed.

6. Bench Test

1) Needle Length
2) Needle Penetration Depth
3) Single Speed (RPM)
4) Preventing of the re-use needle cartridge

VIII. Conclusion

The results of the performance testing described above demonstrate that E-PEN is as safe and effective as SkinPen Precision System (DEN160029) supports a determination of substantial equivalence.