August 29, 2024

Crown Aesthetics
Marie Fogartie
Sr. Director of Regulatory Affairs
5005 Lyndon B. Johnson Frwy, Suite 370
Dallas, Texas 75244

Re: K241400
Trade/Device Name: SkinPen Precision Elite System
Regulation Number: 21 CFR 878.4430
Regulation Name: Microneedling Device For Aesthetic Use
Regulatory Class: Class II
Product Code: QAI
Dated: August 1, 2024
Received: August 1, 2024

Dear Marie Fogartie:

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.

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,

FDA Julie A. Morabito -S

Julie Morabito, 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.

Submission Number *(if known)*

K241400

Device Name

SkinPen Precision Elite System

Indications for Use *(Describe)*

The SkinPen® Precision Elite 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.

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.

510(K) SUMMARY

Date Prepared: May 1, 2024

1. **Submitter and Owner:**

   Bellus Medical LLC, dba Crown Aesthetics
   5005 Lyndon B. Johnson Freeway, Suite 370
   Dallas, Texas 75244, USA

2. **Official Correspondent:**
   Marie Fogartie, Sr. Director of Regulatory Affairs
   Phone: 423-630-2296
   Email: mfogartie@crownlaboratories.com

3. **Submission Type**: Traditional 510(k)

4. **Proprietary Name**: SkinPen® Precision Elite System

5. **Device Classification Information:**

   Classification Name: Microneedling Device for Aesthetic Use
   Regulation Number: 878.4430
   Product Code: QAI
   Device Class: 2

6. **Predicate Device:** K220506 SkinPen Precision System

7. **Device Description**
   The SkinPen® Precision Elite System consists of a microneedling pen handpiece (SkinPen® Precision Elite) and a sterile needle cartridge (SkinPen® Precision Elite Cartridge). The accessories are a charging base with power adaptor and a BioSheath to cover the handpiece.

8. **Indications/Intended use:**
   The SkinPen® Precision Elite 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.

9. **Indications for Use Comparison:**

	Subject Device	**Predicate Device K220506**	**Comparison**
Indication for Use	The SkinPen® Precision Elite 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.	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.

10. Technological characteristics comparison:

Characteristic	Subject Device	Predicate Device K220506	Comparison
Trade Name	SkinPen® Precision Elite System	SkinPen® Precision System	Same
Classification Name	Microneedling device for aesthetic use	Microneedling device for aesthetic use	Same
Classification	2	2	Same
Product Code	QAI	QAI	Same
Regulation No.	878.4430	878.4430	Same
Prescription Use	Yes	Yes	Same
Target Population	Adults age 22 and over	Adults age 22 and over	Same
Target User	Healthcare professionals trained in use of the device	Healthcare professionals trained in use of the device	Same
Environment	Clinical	Clinical	Same
Treatment Area	Face and Neck	Face and neck	Same
Shape of needle cartridge	Round	Round	Same
Use of needle cartridge	Sterile, single use	Sterile, single use	Same
Needles	14 total	14 total	same
Needle Protrusion settings	0–2.5 mm	0–2.5 mm	Same
Max. Needle Length used in the clinical study	2.5mm	2.5mm	Same
Frequency	105-128.3 Hz	105-128.3 Hz	Same
Puncture rate	1470-1797 punctures/sec	1470-1797 punctures/sec	Same
User Interface	LCD screen and On/Off button	On/Off button	Different. The new LCD screen allows users to see whether the cartridge is correctly installed and verify that the cartridge is not being re-used. Software Verification and Validation was performed for this software change. This function does not impact safety or efficacy of the device.
Cartridge authentication/verification	NFC Chip	Manual lock out	Different. Cartridges now can be authenticated with an NFC chip. This function does not impact safety or efficacy of the device.

11. Non-clinical performance testing

Performance testing was conducted on the cartridge's reciprocating rate to ensure that it operates as intended. Testing was also conducted to verify puncture depth of the needle.

12. Clinical Testing Summary

No Clinical testing was conducted as part of this submission.

13. Electrical Safety, Risk Management, Sterility and Software

The SkinPen® Precision Elite System was developed and tested according to the following standards:

IEC 60601-1 Edition 3.2 2020-08
IEC 60601-1-2 Edition 4.1 2020-09
ISO 10993-1 Fifth edition 2018-08
IEC 62304 Edition 1.1 2015-06
ISO 11135 Second edition 2014-07-15
IEC 60601-1-6 Edition 3.2 2020-07

14. Biocompatibility

All patient contacting components of the SkinPen® Precision Elite System have been tested according to ISO 10993-1:2018 and are considered biocompatible.

15. Statement of Substantial Equivalence

The SkinPen® Precision Elite System, the subject device for this submission, is very similar to the predicate device, the SkinPen® Precision System. Changes to the user interface, cartridge connection points, and the addition of an NFC chip for cartridge verification do not impact the device effectiveness, and safety is increased with the use of the NFC chip. There are no changes to the general technology, mechanism of action, or indications for use. Changes to the device are supported through software verification and validation, IEC, biocompatibility, and usability testing. Therefore, the two devices can be considered substantially equivalent.