March 7, 2022

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

Re: K220506
Trade/Device Name: SkinPen® Precision System
Regulation Number: 21 CFR 878.4430
Regulation Name: Microneedling Device for Aesthetic Use
Regulatory Class: Class II
Product Code: QAI
Dated: February 18, 2022
Received: February 22, 2022

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 (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,

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)*
K220506

Device Name
SkinPen® Precision System

Indications for Use *(Describe)*
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.

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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Date Prepared: March 2, 2022

1. Submitter and Owner:

Crown Aesthetics
5005 Lyndon B. JohnsonFreeway
Suite 370
Dallas, Texas 75244, USA

2. Official Correspondent:

Marie Fogartie, Director of Regulatory Affairs
Phone: 423-630-2296
Email: mfogartie@crownlaboratories.com

3. Submission Type: Special 510(k)

4. Proprietary Name: SkinPen® Precision 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: K202243 SkinPen Precision System

7. Device Description:

The SkinPen® Precision System consists of a microneedling pen handpiece (SkinPen® Precision) and a sterile needle cartridge (SkinPen® Precision Cartridge).

The accessories are a charging base and a BioSheath. A SkinPen® Precision System treatment kit is provided separately and contains the following:

- SkinPen® Precision Cartridge: sterile, disposable needle cartridge. Not to be resterilized or reused. (K202243, Class 2, Regulation 878.4430, Product Code: QAI.)
- Lift HG: hydrogel wound dressing (without drugs and/or biologics), to protect against abrasion and friction during the microneedling procedure. May be applied to prevent skin from drying out post procedure. (Class I, 510(k) Exempt, Regulation 878.4022, Product code: NAE.)
- SkinPen® BioSheath: nonsterile, disposable cover for the microneedling pen handpiece to avoid contamination of the SkinPen® Precision.
- Sani-Cloth AF3: Sanitizing cloth available for purchase along with device to sanitize between uses.

8. Indications/Intended use:

The SkinPen® Precision system is a microneedling device and accessories intendedto 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:

The subject and the predicate device (K202243) have identical indications for use statements.

10. Technological characteristics comparison:

Characteristic	Subject Device	Predicate Device K202243	Comparison
Trade Name	SkinPen® Precision System	SkinPen® Precision System	Same
Classification Name	Microneedling device foraesthetic use	Microneedling device foraesthetic 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	Face	Same
Shape of needle cartridge	Round	Round	Same
Needles	14 total solid medical grade stainless steel	14 total solid medical grade stainless steel	Same
Needle Protrusion settings	0–2.5 mm	0–2.5 mm	Same
Max. Needle Length used inthe clinical study	2.5mm	2.5mm	Same
Frequency	6300 RPM to 7700 RPM (105-128.3 Hz)	6300 RPM to 7700 RPM (105-128.3 Hz)	Same

The subject device is identical to the predicate device, except the use of a different disinfecting cloth. The cleaning validation described below demonstrated the device modification raises no safety or effectiveness concerns.

11. Non-clinical performance testing

Cleaning validation testing was conducted for the disinfecting cloth that is the subject of this submission. The cleaning test applied bacteria to the device after being wiped clean with a Sani-Cloth AF3. After applying the bacteria, the devicewas cleaned again with the Sani-Cloth AF3. After application of bacteria on the SkinPen device surface under worst-case conditions of no bio-sheath,

and a minimal cleaning time of 1 minute, it was confirmed that the bacteria were removedfrom the device when cleaned with Sani-Cloth AF3. In conclusion, even if the device is contaminated by bacteria, Sani-Cloth AF3 is considered sufficient for bacterial removal from the device, as the number of bacteria applied to the device was sufficiently high enough to simulate a worst-case scenario of possible microbial contamination. The new Sani-Cloth AF3 shows the same or improved results than the previously used Sani-Cloth HB.

12. Clinical Testing Summary

No Clinical testing was conducted as part of this submission.

13. Statement of Substantial Equivalence:

Crown Aesthetics has demonstrated that the SkinPen® Precision System has the same device classification, same intended use and technological characteristics as the predicate device. The only change in this submission is the cloth used for disinfection is shown effective in a validation report provided with this application.