April 2, 2021

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

Re: K202243
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 4, 2021
Received: February 5, 2021

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,

for Lixin Liu, Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K202243

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.

Section 5: 510(K) SUMMARY K202243

Date Prepared: April 1, 2021

1. Submitter and Owner:

Crown Aesthetics
5005 Lyndon B. Johnson Freeway
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: Traditional 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: K180778 Exceed Microneedling Device
Reference Device: DEN 160029 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. (DEN160029, 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.

8. Indications/Intended use:

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.

9. Indications for Use Comparison:

	Subject Device K202243	Predicate Device K180778
Indication for Use	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.	The Exceed is a microneedling device and accessories is intended for the treatment of wrinkles in Fitzpatrick skintypes I, II and/or III in the following facial areas: glabellar frown lines, periorbital lines and cheek folds in adults aged 22 years or older

10. Technological characteristics comparison:

Characteristic	Subject Device K202243	Predicate Device K180778
Trade Name	SkinPen® Precision System	Exceed Microneedling device
Classification Name	Microneedling device for aesthetic use	Microneedling device for aesthetic use
Classification	2	2
Product Code	QAI	QAI
Regulation No.	878.4430	878.4430
Prescription Use	Yes	Yes
Target Population	Adults age 22 and over	Adults age 22 and over
Target User	Healthcare professionals trained in use of the device	Healthcare professionals trained in use of the device
Environment	Clinical	Clinical
Treatment Area	Face and Neck	Face
Shape of needle cartridge	Round	Squared
Needles	14 total solid medical grade stainless steel	6 needles, squared arrangement medical grade stainless steel
Needle Protrusion settings	0–2.5 mm	0 - 1.9 mm
Max. Needle Length used in the clinical study	2.5 mm	1.5 mm
Frequency	6300 RPM to 7700 RPM (105-128.3 Hz)	6300 RPM to 7700 RPM (100-150 Hz)

11. Non-clinical performance testing

The SkinPen® Precision is subject to the Special Controls listed in 21 CFR 878.4430(b). A new, additional cleaning and disinfection method has been validated and is contained within the instructions for use, however no other changes have been made to the technological characteristics of the device since DEN160029. The differences in technological characteristics between the subject and predicate device, including needle count, configuration, and maximum protrusion settings, did not necessitate additional non-clinical testing as compliance to the Special Controls was previously demonstrated in DEN160029.

12. Clinical Testing Summary

A clinical study was conducted to support the safety and effectiveness of the SkinPen Precision System for the treatment of acne scars on the face in DEN160029.

A clinical study has since been conducted to support the safety and effectiveness of the SkinPen Precision System for the treatment of wrinkles on the neck.

The single center study was conducted on a total of 35 subjects (2 male and 33 female), aged 44 years and older from various ethnic groups with multiple skin tones (pale to dark skin). Treatments were given on day 1, day 30, day 60, and day 90 with follow-up visits at 1 month and 3 months after the last treatment. Under direct supervision of a licensed Physician, treatments were conducted by a trained aesthetician (skin care specialist). The face and neck were cleaned and numbed prior to treatment. A thin layer of Skinfuse Lift HG was applied prior to treatment area to protect against abrasion and friction during the procedure. The aestheticians were instructed to treat at depths of up to 2.5 mm. Following treatment, Skinfuse Lift HG was applied to prevent the skin from drying out post procedure.

Table 1: Summary of Demographic Information Per Protocol

	SkinPen Precision System	
N	32	
Age (years)		
Mean (standard deviation)	56.3 (5.0)	
Minimum, Median, Maximum	44, 56.5, 65	
	N	(%)
Sex		
Male	2	6.3
Female	30	93.8
Ethnicity		
Hispanic or Latino	4	12.5
Not Hispanic or Latino	28	87.5
Race		
Other	4	12.5
White or Caucasian	28	87.5
Fitzpatrick Skin Type		
II	24	75.0
III	4	12.5
IV	4	12.5

At each clinical visit, digital images were taken of each subject's wrinkles on the neck. These images were graded by two separate independent blinded Board Certified Physicians after completion of the study using the following assessment tools and timepoints [Tables 2-5]. The results of the study are provided in Tables 6-10.

Table 2: Study Endpoints

Primary Effectiveness Endpoints	G. Lemperle Wrinkle Scale graded by two blinded graders using photographs taken at day 1 and 3-months post-treatment
Secondary Effectiveness Endpoint	Clinician's Global Aesthetic Improvement Assessment graded by two blinded graders using photographs taken at day 1 and 3-months post-treatment
	Subject Global Aesthetic Improvement Scale completed by subjects at 1-month post-treatment, and 3-months post-treatment
	Patient Satisfaction Questionnaire completed by subjects at 1-month post-treatment and 3-months post-treatment
Safety Endpoint	Subject safety diaries provided to the subject at each treatment visit (day 1,30, 60 and 90) and completed for 30 days to record treatment responses
	Adverse event monitoring at each visit; day 1, day 30, day 60, day 90, 1-month post-treatment and 3 months post-treatment

Subjects had wrinkling assessed on the neck using the G. Lemperle Wrinkle Assessment Scale.

Table 3: Assessment of Wrinkling – G. Lemperle Wrinkle Scale

Class	Description
0	No wrinkles
1	Just perceptible wrinkle
2	Shallow wrinkles
3	Moderately deep wrinkle
4	Deep wrinkle, well-defined edges
5	Very deep wrinkle, redundant fold

At 1 month post-treatment and 3 months post-treatment, subjects also participated in the following procedures:

- Clinician's Global Aesthetic Improvement Scale

Table 4: Clinician's Global Aesthetic Improvement Scale

Rating	Description
1	**Very Much Improved:** Optimal cosmetic result in this subject.
2	**Much Improved:** Marked improvement in appearance from the initial condition, but not completely optimal for this subject.
3	**Improved:** Obvious improvement in appearance from initial condition, but are-treatment is indicated.
4	**No Change:** The appearance is essentially the same as the original condition.
5	**Worse:** The appearance is worse than the original condition.

- Subject's Global Aesthetic Improvement Scale

Table 5: Subject Global Aesthetic Improvement Scale

Rating	Description
1	**Very Much Improved:** Optimal cosmetic result.
2	**Much Improved:** Marked improvement in appearance from the initial condition, but not completely optimal.
3	**Improved:** Obvious improvement in appearance from initial condition.
4	**No Change:** The appearance is essentially the same as the original condition.
5	**Worse:** The appearance is worse than the original condition.

- Patient Satisfaction Questionnaire

  Subjects completed a Sponsor-provided questionnaire regarding improvement in wrinkles, satisfaction with the treatment and willingness to recommend the treatment to friends and family members.

Results:

Safety:

a. What side effects were seen in the clinical study?

Common Treatment Responses on the face and neck:

Common Treatment responses of dryness, redness, burning sensation and itchiness which lasted the duration of 1-3 days. Reactions of tenderness and peeling/flaking occurred for the duration of 1-7 days.

The following common treatment responses were reported in the subject safety diaries which were sent home with the subject:

- Dryness in 7/32 (22%) subjects lasting from 1-3 days
  - These responses were reported by 6 subjects with FST II, 1 subject with FST IV
- Redness in 2/32 (6%) subjects lasting from 1-3 days
  - These responses were reported by 2 subjects, 1 subject with FST II, 1 subject with FST IV
- Itching in 1/32 (3%) subjects with FST II, lasting from 1-2 days
- Peeling was reported in 8/32 (22%) of subjects lasting 1-3 days
  - These responses were reported by 8 subjects, 5 subjects with FST II, 1 subject with FST III, 2 subjects with FST IV
- Tenderness that lasted 1-4 days in 1/32 (3%) of Subjects , with FST II
- Burning in 2/32 (6%) of subjects lasting 1-3 days
  - These responses were reported by 2 subjects with FST IV

b. What adverse events were seen in the clinical study?

At the 3-month post-treatment visit, no adverse events were seen.

No adverse events related to the SkinPen Precision treatment were observed on the face and neck during the study.

c. What are other possible adverse events?

Although not seen in the clinical study, patients may experience red and flushed skin, skin tightness and mild sensitivity to touch (such as itching, burning, stinging, tingling), scaling/dryness, redness, edema and tenderness/discomfort.

Benefits:

What will a SkinPen Precision Treatment accomplish, and what did the clinical study show?

The study doctors reported using the G. Lemperle Wrinkle Scale:

Results of the photo grading indicated a significant improvement in wrinkles on the neck area assessment at 3 months post- treatment.

Table 6: Results of Photo Grading of G. Lemperle Wrinkle Scale for SkinPen Precision System

Detail	Time Point	N	Mean	Standard Deviation	Min	Median	Max
Neck	Day 1	32	3.31	0.74	2.00	3.25	5.00
	3 Mo. Post-Treatment	32	2.45	0.93	1.00	2.00	4.50

Table 7: Change from Baseline for Photo Grading of G. Lemperle Wrinkle Scale for SkinPen Precision System

Detail	Time Point	N	Subjects graded as having ≥1 grade improvement
Neck	3 Mo. Post-Treatment	32	16 (50%)

Clinician's Global Aesthetic Improvement Assessment:

Treatment with SkinPen Precision produced an improvement in CGAIS scores at 3 months post-treatment. At three-months post-treatment evaluation, 31.5% of subjects received a '3: improved' grading and 57% received a grading of '4: no change' relative to pre-treatment. Four subjects (11.5%) received a grading of '2: much improved'.

Subjects reported using the Subject Global Aesthetic Improvement Scale:

Treatment with SkinPen Precision produced an improvement in Subject GAIS scores at 3-months post-treatment. At 3-months post-treatment, 22 (68.8%) subjects reported some percentage of improvement in the appearance of their wrinkles, with 10 (31.3%) subjects reporting no change.

Subjects reported using the Patient Satisfaction Questionnaire:

The results of the patient satisfaction questionnaire for all subjects indicated that a greater number of subjects selected favorable responses regarding treatments at 1 month and 3 months post-treatment for the following inquiries:

- **Question 1: Do you notice any improvement in how your fine lines and wrinkles look in the treated area?**

Table 8: Results of Patient Satisfaction Questionnaire - Question 1

Time Point	Yes [N (%)]	No [N, (%)]
1-Month Post-Treatment	30 (93.8)	2 (6.3)
3-Months Post-Treatment	23 (71.9)	9(28.1)

- **Question 2: How would you characterize your satisfaction with the treatment?**

Table 9: Results of Patient Satisfaction Questionnaire – Question 2

Time Point	N	Favorable (+) N (%)	Unfavorable (-) N (%)	Neutral N (%)
1 Month Post-Treatment	32	28 (87.5)	3 (9.4)	1 (3.1)
3 Months Post-Treatment	32	24 (75.0)	6 (18.8)	2 (6.3)

- **Question 3: Would you recommend this treatment to your friends and family members?**

Table 10: Results of Patient Satisfaction Questionnaire – Question 3

Time Point	Yes [N (%)]	No [N, (%)]
1-Month Post-Treatment	25 (80.6)	6 (19.4)
3-Months Post-Treatment	21 (65.6)	11 (34.4)

Subjects were informed of the following potential common treatment responses in the informed consent process: skin will be red and flushed similar to a moderate sunburn, skin tightness and mild sensitivity to the touch, redness, burning, tingling, stinging, itching, and/or scaling/dryness, edema (swelling), tenderness/ discomfort, a possibility of developing an infection (an increase in redness, warmth, itching, or pus formation). The diaries included space for daily recording of observations for the 30 days in between treatment visits. Adverse events were assessed by the investigator at each subsequent visit.

13. Statement of Substantial Equivalence:

Crown Aesthetics has demonstrated that the SkinPen® Precision System has the same device classification, same intended use and basic technological characteristics as the predicate device. The new indication for use is supported by clinical evidence.