March 6, 2025

Dermaroller GmbH
% Barbara A. Binzak Blumenfeld
Co-Leader and Shareholder
Buchanan
1700 K Street, N. W., Suite 300
Washington, District of Columbia 20006-3807

Re: K241790
Trade/Device Name: XCELLARISPRO TWIST microneedling device
Regulation Number: 21 CFR 878.4430
Regulation Name: Microneedling Device For Aesthetic Use
Regulatory Class: Class II
Product Code: QAI
Dated: January 21, 2025
Received: February 4, 2025

Dear Barbara A. Binzak Blumenfeld:

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

Wilmarie Flores, Ph.D.
Assistant Director (*Acting*)
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)*

K241790

Device Name

XCELLARISPRO TWIST microneedling device

Indications for Use *(Describe)*

The XCELLARISPRO TWIST microneedling device and accessories is intended to be used as a treatment to improve the appearance of facial acne scars in Fitzpatrick skin types I, II, III and IV in adults aged 22 years or older and for treatment of wrinkles in Fitzpatrick skin types 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.

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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XCELLARISPRO TWIST 510(k) Summary

Date Prepared: March 6, 2025

Device Trade Name: XCELLARISPRO TWIST microneedling device

Common Name: Microneedle device for aesthetic use

Classification Name: Powered Microneedle Device

Regulation Number: 878.4430

Product Code(s): QAI

Legally Marketed Predicate Devices

K182407	Exceed microneedling device
K180778	Exceed microneedling device
DEN160029	SkinPen Precision system

Sponsor Contact Information

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1. Device Classification Information

A microneedling device for aesthetic use is a device using one or more needles to mechanically puncture and injure skin tissue for aesthetic use. This classification does not include devices intended for transdermal delivery of topical products such as cosmetics, drugs, or biologics.

2. Indications for Use Statement

The XCELLARISPRO TWIST is a microneedling device and accessories that is intended to be used as a treatment to improve the appearance of facial acne scars in Fitzpatrick skin types I, II, III and IV in adults aged 22 years or older and for the treatment of wrinkles in Fitzpatrick skin types 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.

The device is a prescription device and complies with 21 C.F.R. § 801.109.

3. Device Description and Operation

The XCELLARISPRO TWIST is a microneedling device and intended to create many, very tiny, microscopic punctures in the epidermal and dermal layers of the skin using sterile stainless-steel needles. The XCELLARISPRO TWIST has 4 component parts and 2 consumables. Component parts: (1) handpiece, (2) control unit, (3) power supply and (4) foot switch. Consumables: (1) sterile, single-use needling module (Ethylene oxide sterilized) and (2) disposable barrier sleeves that cover the handpiece during each patient use.

The surfaces of the control unit and the handpiece are made of materials which can be cleaned and disinfected properly between patients.

The assembly of the microneedling system is completed by connecting the handpiece to the control unit. The control unit switches the device on and off and contains the power source (100-240 V). The control unit adjusts the frequency of the needle stroke from 50-150 Hz (recommended working frequency is 100-150 Hz) using an easy to use turning knob. A power supply unit is added to the system for electrical operation, and a foot switch is provided as an operating option for the user. The handpiece contains the motor that moves the needles and a needle protrusion gauge that allows the user to control the depth of the needle protrusion from 0 – 2.5 mm, with a recommended maximum needle penetration depth of 1.5 mm. The handpiece contains a scale that allows the operator to adjust the needle protrusion depth.

The puncture frequency is the rate at which the needles are driven into the skin. The XCELLARISPRO TWIST microneedling device has a puncture frequency range of 50-150 per second and can be adjusted steplessly. The actual number of punctures per second may vary by ± 10% from the value set on the handpiece.

The needling module contains a needle cushion containing 6 stainless steel microneedles in squared arrangement, each 2.5 mm in length, and it is the patient-touching component. The recommended needle protrusion is 1.5 mm. The needling module is mounted into the handpiece and safely secured by a metal flap with magnets. The needling module is provided sterile and for single use only. It can only be used for microneedling treatments.

A lasting treatment success can only be expected after several treatments. Usually 3-5 treatments are performed, but depending on the facial scar or wrinkle depth and structure, more (or fewer) treatments may be necessary.

The interval between two treatments should be at least 4-6 weeks to complete the wound healing cascade.

The device is a prescription use device and complies with 21 C.F.R. § 801.109.

Intended Use/ Indications for Use

The XCELLARISPRO TWIST microneedling device and accessories is intended to be used as a treatment to improve the appearance of facial acne scars in Fitzpatrick skin types I, II, III and IV in adults aged 22 years or older and for treatment of wrinkles in Fitzpatrick skin types 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.

Indications for Use Comparison

The indications for use of the subject device are the same as for the predicate devices: Treatment to improve the appearance of facial acne scars in Fitzpatrick skin types I, II, III and IV in adults aged 22 years or older (K182407 and DEN160029) and treatment of wrinkles in Fitzpatrick skin types 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 K180778).

Technological Comparison

Substantial Equivalency and Comparison of Technological Similarities & Differences

Key Similarities

a) XCELLARISPRO TWIST Microneedling System vs. Exceed Microneedling device (K182407 and K180778)

• The device classification (generic description) and basic technologies are equivalent in that both devices are microneedling systems containing >1 needle that mechanically punctures or injures the skin for aesthetic use.

• Identical Device Product Code and Device Classification (QAI)

• Identical intended use

• Intended for prescription use

• Location of use (Face)

• Sterilization method for needling modules (Ethylene oxide)

• Identical recommended needle penetration depth (1.5 mm)

b) XCELLARISPRO TWIST Microneedling System vs. SkinPen® Precision System (DEN160029)

• The device classification (generic description) and basic technologies are equivalent in that both devices are microneedling systems containing >1 needle that mechanically punctures or injures the skin for aesthetic use.

• Identical Device Product Code and Device Classification

• Identical intended use

• Intended for prescription use

• Location of use (Face)

• Sterilization method for needling modules (Ethylene oxide)

• Identical recommended needle penetration depth (1.5 mm)

• Identical maximum needle length (2.5 mm)

Differences

a) XCELLARISPRO TWIST Microneedling System vs. Exceed Microneedling device (K182407 and K180778)

Although the devices share the basic generic description and technologies they do differ in several areas. Differences have been addressed by the manufacturer through the applicable safety standards (General controls and mitigation measures) and through non-clinical performance testing (Special controls).

• Frequency – the frequency range (oscillation) of the XCELLARISPRO TWIST is greater than the frequency range of the predicate device, the Exceed microneedling device. However, the recommended working frequency is similar and the max. frequency is identical.

• Needle protrusion setting – the needle protrusion setting of the proposed device is within the range of the predicate device. The predicate device used a maximum of 1.5 mm in its reported clinical study and Instructions for Use and therefore is comparable to the proposed device.

Non-clinical performance testing demonstrates the needle protrusion setting of the proposed device is reproduceable within the technical specifications of the device. • Maximum needle length – Non-clinical performance testing demonstrates that the proposed device does not pose any undue or additional risks and is effective.

Although there are differences between the proposed device and the predicate device Exceed device, general controls of the FD&C Act and “Special controls” including non-clinical performance testing demonstrate that the Dermaroller XCELLARISPRO TWIST raises no new question in relation to safety and effectiveness compared to the predicate device.

b) XCELLARISPRO TWIST Microneedling System vs. SkinPen® Precision System (DEN160029)

Although the devices share the basic generic description and technologies they do differ in several areas. Differences have been addressed by the manufacturer through the applicable safety standards (General controls and mitigation measures) and through non-clinical performance testing (Special controls).

• Frequency – the frequency range (oscillation) of the XCELLARISPRO TWIST is different than the frequency range of the predicate device, the SkinPen® Precision System. However, the frequency is in the similar range.

• Needle protrusion setting – the needle protrusion setting of the proposed device is within the range of the predicate device. The predicate device used a maximum of 1.5 mm in its reported clinical study and Instructions for Use and therefore is comparable to the proposed device. Non-clinical performance testing demonstrates the needle protrusion setting of the proposed device is reproduceable within the technical specifications of the device.

• Maximum needle length – Non-clinical performance testing demonstrates that the proposed device does not pose any undue or additional risks and is effective.

Although there are differences between the proposed device and the predicate device SkinPen® Precision System, general controls of the FD&C Act and "Special controls" including non-clinical performance testing demonstrate that the Dermaroller XCELLARISPRO TWIST raises no new question in relation to safety and effectiveness compared to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

1. Non-Clinical Performance Testing

To demonstrate safety and effectiveness and support substantial equivalence, the XCELLARISPRO TWIST microneedling device has undergone non-clinical performance testing in line with recognized standards in terms of general requirements, biocompatibility, electrical safety and software.

In combination with the general controls of the Federal Food, Drug, and Cosmetic Act, the XCELLARISPRO TWIST is subject to the following special controls (21 C.F.R. § 878.4430(b)(1)-(10)):

1. The technical specifications and needle characteristics are identified, including needle length, geometry, puncture rate and maximum protrusion depth.

2. Non-clinical performance data demonstrate that the device performs as intended under anticipated conditions of use.

The following performance characteristics are tested:

i. Accuracy of needle protrusion depth and puncture rate in pig skin with high-speed camera measurements;

ii. Safety features built into the device to protect against cross-contamination, including fluid ingress protection due to a bellows; and

iii. Identification of the maximum safe needle protrusion depth for the device in pig skin with high-speed camera measurement.

3. Performance data demonstrate the sterility of the patient-contacting components of the device according to ISO 11737-2, ISO 11135.

4. Performance data supports the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the intended shelf life according to ISO 11607-1.

5. Performance data demonstrate the electrical safety and electromagnetic compatibility (EMC) of all electrical components of the device according to IEC 60601-1 and IEC 60601-1-2.

6. Software verification, validation, and hazard analysis.

7. The patient-contacting components of the device were demonstrated to be biocompatible by testing that evaluated cytotoxicity, irritation, and sensitization, acute systemic toxicity and material-mediated pyrogenicity per the FDA guidance document "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.'"

8. Cleaning and disinfection validations were performed for reusable components of the device.

9. Labeling includes the following:

i. Information on how to operate the device and its components and the typical course of treatment;

ii. A summary of the device technical parameters, including needle length, needle geometry, maximum penetration depth, and puncture rate;

iii. Validated methods and instructions for reprocessing of any reusable components;

iv. Disposal instructions; and

v. Shelf life.

10. Patient labeling includes:

i. Information on how the device operates and the typical course of treatment;

ii. The probable risks and benefits associated with use of the device; and

iii. Post-operative care instructions.

2. Clinical Performance Testing

No clinical studies were performed to test the XCELLARISPRO TWIST microneedling device.

The subject device raises no new questions of safety or effectiveness and has been found to be substantially equivalent to the predicate device.