August 25, 2025

Dermalogica, LLC
Nelson Torres
Director, Medical Tools and Products
1535 Beachey Pl
Carson, California 90746

Re: K243800
Trade/Device Name: PRO Pen Microneedling System (6883)
Regulation Number: 21 CFR 878.4430
Regulation Name: Microneedling Device For Aesthetic Use
Regulatory Class: Class II
Product Code: QAI
Dated: May 15, 2025
Received: May 16, 2025

Dear Nelson Torres:

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,

Jodie Giordano -S

Jodie Giordano, Ph.D.
Acting 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)*

K243800

Device Name

PRO Pen Microneedling System (6883)

Indications for Use *(Describe)*

The PRO Pen Microneedling 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 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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Applicant Contact Details

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Contact Telephone: (210) 912-7017
Contact Name: Nelson Torres
Contact email: nelson.torres@dermalogica.com
Prepared: August 25, 2025

Device Details

Trade Name: PRO Pen Microneedling System (6883)
Common Name: Microneedling device for aesthetic use
Classification Name: Powered Microneedle Device
Regulation Number: 878.4430
Product Code(s): QAI

Legally Marketed Predicate Device

Predicate #: K230420
Name: Dr. Pen Microneedling System
Product Code(s): QAI

Device Description Summary

The PRO Pen microneedling system is a microneedling device and disposable 14-pin cartridges intended for use in adults. The device can be powered with a rechargeable battery or a provided power adapter. The device uses disposable single-use, sterile 14-pin (14-needle) cartridges made of polymer and stainless steel.

Intended Use/Indications for Use

The PRO Pen Microneedling 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 and older.

Indications for Use Comparison

Indications for use of the subject device are identical as for the predicate device.

Technological Comparison

The PRO Pen Microneedling System is identical to the predicate device in the following characteristics:

- Indications for use
- intended use location
- primary power source
- battery charger
- control mechanism
- puncture rate
- number of needles and needle gage
- needle material
- needle geometry

- needle arrangement
- needle spacing
- sterile state and sterilization method
- cross contamination protection

The PRO Pen Microneedling System differs from the predicate device in the following characteristics:

- Alternate Power Source: The PRO Pen can run with an AC adapter directly from mains power in addition to the rechargeable battery, as opposed to the predicate device, which can only be operated with a rechargeable battery.
- Depth Settings and Max Needle Depth: The PRO Pen can be adjusted in 0.2mm increments up to a maximum penetration depth of 1.5mm, which is shorter than the predicate device's maximum penetration depth of 2.0mm
- Shelf Life: The 14-pin cartridges of the PRO Pen have a shelf life of 3 years, which is greater than the predicate device's shelf life of 2 years.

Non-clinical and/or Clinical Tests Summary & Conclusions

The following performance tests were conducted with the PRO Pen Microneedling System in accordance with special controls for microneedling devices in 21 CFR 878.4430:

- Needle Penetration Depth Accuracy,
- Puncture rate characterization
- Vacuum and fluid ingress prevention evaluation,
- Sterility of patient contacting components,
- Aging distribution and shelf-life testing,
- Electromagnetic compatibility and electrical safety,
- In vitro cytotoxicity
- Material characterization through extractables and leachables, with a corresponding toxicological risk assessment of the findings
- Human patch testing for irritation
- Human repeat insult patch testing (HRIPT)
- Cleaning and disinfection validation

The PRO Pen Microneedling system successfully passed all performance tests listed above.

The PRO Pen Microneedling System complies with FDA requirements under special controls detailed in 21 CFR 878.4430, including needle penetration depth accuracy, puncture rate, cross contamination/fluid ingress prevention, packaging durability, cleaning and disinfection validation, electromagnetic compatibility, and shelf-life testing. Human patch and repeat insult patch testing of the patient-contacting materials yielded no irritation or sensitization reactions and concluded the materials can be classified as non-irritating and non-sensitizing. The system demonstrated reliable performance across all critical tests, including vacuum prevention, fluid ingress, packaging integrity, and needle retention. Cleaning and disinfection procedures were validated, confirming the device can be safely cleaned and disinfected to reduce contamination risks.

The device also passed EMC and electrical safety testing, confirming safe operation in healthcare environments.

Collectively, the results of all clinical and non-clinical performance testing conducted demonstrate that the PRO Pen Microneedling System is as safe, effective, and performs as well as the predicate device.