March 19, 2025

Campomats S.r.l.
% Chiara Violini
Consultant
White Lab S.r.l.
via del Consorzio, 41
Falconara Marittima, AN 60015
Italy

Re: K243472
Trade/Device Name: 1NEED Pro
Regulation Number: 21 CFR 878.4430
Regulation Name: Microneedling device for aesthetic use
Regulatory Class: Class II
Product Code: QAI
Dated: December 19, 2024
Received: December 19, 2024

Dear Chiara Violini:

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.
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.

510(k) Number *(if known)*
K243472

Device Name
1NEED Pro

Indications for Use *(Describe)*

The 1NEED Pro 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 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) #: K243472

510(k) Summary

Prepared on: 2025-02-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	CAMPOMATS S.R.L.
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Correspondent Contact Telephone	+390710971877
Correspondent Contact	Mrs. Chiara Violini
Correspondent Contact Email	c.violini@endoengineering.it

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	1NEED Pro
Common Name	Powered microneedle device
Classification Name	Microneedling device for aesthetic use
Regulation Number	878.4430
Product Code(s)	QAI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate#	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K230420	Dr.pen Microneedling System	QAI

Device Description Summary

21 CFR 807.92(a)(4)

The 1NEED Pro is a minimally invasive microneedling device that mechanically creates microscopic punctures in the epidermal and dermal layers of the skin by means of micro-needles in a reciprocating cartridge head. The 1NEED Pro is comprised of a reusable pen body, a sterile, single use microneedling cartridge and a power adapter. The microneedling cartridge is attached to the pen body and activated with an On/Off button. The depth of needle penetration can be adjusted by the user depending on the condition of the skin being treated. Charging is accomplished by attaching the 1NEED Pro pen body to the power adapter.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The 1NEED Pro 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 or older.

Indications for Use Comparison 21 CFR 807.92(a)(5)

1NEED Pro device has the same intended use of the legally marketed predicate devices.
The 1NEED Pro 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 or older

Technological Comparison 21 CFR 807.92(a)(6)

1NEED Pro has the same technological characteristics and microneedling is the technological principle for both the subject and predicate device (K230420).

The 1NEED Pro and the predicate are for identical uses and rely on the same mode of action. The devices include disposable needle cartridges with design features to mitigate the likelihood of cross-contamination between patients and to prevent needle depth greater than 2 mm.

The subject and the predicate have the same technological characteristics including:

- Intended Location of use: Face
- Power source (pen body): Rechargeable Li-ion battery
- Power Source (Battery Charger): AC Powered
- Control mechanism: Microprocessor; embedded software
- Single Speed (RPM): 6300- 7700
- Puncture Rate: 105 -128 stamps/second
- Microneedling Cartridge: Sterile, Single Use
- Number of needles and geometry: 14 (radially arranged)
- Needle Gauge: 34 Ga
- Needle Material: Stainless Steel
- Needle Shape Geometry: Straight, cylindrical body with a conical tapered, sharp point
- Needle spacing: 2 mm spacing/3.96 mm2 per needle
- Penetration depth: 1.5 mm (Recommended)
- Max. needle Depth setting: 2,0 mm
- Penetration Depth Selection: 9 depth settings; 0 mm to 2.0 mm in 0.25 mm increments
- Sterility: Not sterile device, Sterile cartridges (EO)
- Shelf life: 2 years (cartridge)
- Barrier- Cross/Contamination: Protective Sleeve (Disposable)
- Treatment protocol 3 treatments spaced 4 weeks apart
- Bench tests:
• Motor Speed Puncture Rate Testing
• Extension Accuracy Testing
• Needle Bonding Strength Test
• Use Life Testing
• Cartridge Life Testing
• Anti-suction Testing
• Microbial Ingress Testing

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Bench testing included the following:

- Motor Speed Puncture Rate Testing
- Needle Penetration Depth and Extension Accuracy Testing
- Needle Bonding Strength Test
- Use Life Testing
- Cartridge Life Testing
- Anti-suction Testing
- Microbial Ingress Testing

Conclusion

Nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed predicate device.