February 23, 2024

Mt.Derm GmbH
Stefan Polland
Regulatory Affairs Manager
Blohmstr. 37-61
Berlin, 12307
Germany

Re: K233709
Trade/Device Name: Exceed Unlimited
Regulation Number: 21 CFR 878.4430
Regulation Name: Microneedling Device For Aesthetic Use
Regulatory Class: Class II
Product Code: QAI
Dated: January 24, 2024
Received: January 24, 2024

Dear Stefan Polland:

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.

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,

FDA Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and 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)*

K233709

Device Name

Exceed Unlimited

Indications for Use *(Describe)*

The Exceed Unlimited is a microneedling device and accessories intended 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 Exceed Unlimited is a microneedling device and accessories 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.

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.

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510(k) Summary
K233709

Executive Summary

Submitter's Name: MT.DERM GmbH

Submitter´s Contact: Stefan Polland

Submitter's Address: Blohmstr. 37-61, 12307 Berlin, Germany

Submitter´s Telefon: +49 30 7676 220 171

Device Trade Name: Exceed Unlimited

Submition Date: 24th Jan, 2024

Submission update: 16th Feb, 2024

1. Device Classification Information:

Regulation Number	Device Classification name	Device Class	Product Code	Generic description	Classification Panel	Type
21 CFR 878.4430	Microneedling device for aesthetic use	Class 2	QAI	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.	General & Plastic Surgery	Traditional 510 (k)

2. Device Description

The Exceed Unlimited device is intended to create many, very tiny, microscopic punctures in the epidermal and dermal layers of the skin using sterile stainless steel needles.

The Exceed Unlimited device consists of 7 component parts; Handpiece, sterile single use Safety needle cartridge, Handpiece holder, Barrier Sleeve, Battery, Charger incl. USB cable, power supply.
The handpiece contains a motor that moves the needles. The handpiece receives power via a Li-Ion battery with an output of 3,7 V. The battery charger receives power from a standard 100-240V, 50-60Hz, 0.45A wall socket transformer with an USB output of 5 V, 3.2A.

The frequency of the handpiece can be adjusted from 100-150Hz and is indicated on a display.
The needle penetration is adjusted by the needle protrusion setting dial, which can be adjusted between 0.0 (min.) and 1.9 mm (max.).

The standard safety needle cartridge (6-needle plate) contains 6 stainless steel microneedles of 1.5 mm length (0.35 mm gauge) and an internal safety membrane. The safety needle cartridge is screwed into the handpiece. The safety needle cartridge is sterile and for single use ONLY.

3. Indications/Intended Use

The Exceed Unlimited is a microneedling device and accessories intended 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 Exceed Unlimited is a microneedling device and accessories 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.

The device is a prescriptive device and complies with 21CFR 801.109.

4. Predicate Device

Exceed K182407

The Exceed Microneedling device is a microneedling device and accessories intended 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 Exceed Microneedling device is a microneedling device and accessories 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.

Intended use applies exclusively to the following patient groups: Adult men and women aged 22 years or older who are in good health.

The device is a prescription device and complies with 21CFR 801.109.

5. Technological Characteristics

Property	Exceed Unlimited	Exceed Microneedling Device	Significant differences
Device Manufacturer	MT.DERM GmbH Blohmstr. 37 - 61, 12307 Berlin, Germany	MT.DERM GmbH Blohmstr. 37 – 61, 12307 Berlin, Germany	Not applicable
Device Trade Name	Exceed Unlimited device	Exceed microneedling device	Not applicable
510(K) Number		(A) K182407 (B) K180778	Not applicable
Device Classification name	Microneedling device for aesthetic use	Microneedling device for aesthetic use	Identical
Device Product Code	QAI	QAI	Identical
Device Classification	Class II	Class II	Identical
Regulation number	21 CFR 878.4430	21 CFR 878.4430	Identical
Use	Prescription	Prescription	Identical
Intended Location of Use	Face	Face	Identical
Intended use and Indications	The Exceed Unlimited device is a microneedling device and accessories intended 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 Exceed Unlimited device is a microneedling device and accessories 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.	K180778: The Exceed Microneedling device is a microneedling device and accessories intended 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. K182407: The Exceed Microneedling device is a microneedling device and accessories 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.	Identical
Geometry	6 needles, squared arrangement	6 needles, squared arrangement	Identical

Property	Exceed Unlimited	Exceed Microneedling Device	Significant differences
Needle protrusion setting	0 - 1.9 mm	0 - 1.9 mm	Identical
Maximum needle penetration (maximum needle length)	1.5mm	1.5 mm	Identical
Frequency	100-150 Hz (±10%)	100-150 Hz (±10%)	Identical

6. Substantial Equivalency and Comparison of Technological Similarities & Differences

6.1. Key Similarities.

i. The device classification (generic description) and basic technologies are equivalent in that both devices are micro needling systems containing >1 needle that mechanically punctures or injures the skin for aesthetic use.
ii. Identical intended use.

iii. The depth of penetration of the needles (needle length) is equivalent – 1.5mm

iv. Intended for prescription use.
v. Location of use (Face)
vi. Identical needle configuration
vii. Identical needle protrusion setting
viii. Identical Frequency

6.2. Differences.

Although the systems share the basic technology they do differ in two major areas:

i. Power Supply – Exceed Microneedling device was supplied directly by a wall plug. Exceed Unlimited is supplied by rechargeable battery.
ii. Control - Exceed Microneedling device was controlled by a separate control unit. Exceed Unlimited is directly controlled with the hand piece.

This difference has been addressed by the manufacturer through the applicable safety standards (General controls and mitigation measures).

Although there are differences between the proposed device, Exceed Unlimited, and predicate device, Exceed Microneedling Device (K182407), General controls of the FD&C Act and "Special controls" listed below demonstrate that the Exceed Unlimited device raises no new questions in relation to safety and efficacy compared to the predicate device.

7. General controls and mitigation measures

To demonstrate safe and effective performance and support substantial equivalence the Exceed Unlimited device has undergone a number of non-clinical performance tests in line with recognized standards in terms of general requirements, biocompatibility, electrical safety and software.
The following non-clinical performance data is provided in support of the substantial equivalence determination.

7.1. Summary of Risk and mitigation measures

Identified Risk to Health	Mitigation Measures	Evidence
Adverse tissue reaction	Biocompatibility evaluation	ISO 10993-5 Third edition 2009-06-01 ISO 10993-7:2008 ISO 10993-10: 2010 ISO 10993-11:2017 FDA - Blue Book Memorandum #G95-1
	Labeling	ISO 15223-1 Fourth edition 2021-07 ISO 20417:2021, Corrected version 2021-12
Cross contamination and infection	Sterilization validation	ISO 11135:2014 + Amd.1:2018
	Reprocessing validation	A cleaning validation was performed for reusable components of the device. (Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling)
	Non-clinical performance testing	Non-clinical performance data demonstrates that the device performs as intended under anticipated conditions of use. The following performance characteristics are tested i. Accuracy of needle penetration depth and puncture rate in pig skin with high - speed camera measurement; ii. Safety features built into the device to protect against cross-contamination, including fluid ingress protection due to a safety membrane; and

Identified Risk to Health	**Mitigation Measures**	**Evidence**
		iii. Identification of the maximum safe needle penetration depth for the device in pig skin with highspeed camera measurement.
	Shelf life testing	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 Second edition 2019-02 ISO 11607-2 Second edition 2019-02
	Labeling	Section 13 Proposed labeling ISO 15223-1 Fourth edition 2021-07 ISO 20417:2021, Corrected version 2021-12
Electrical shock or Electromagnetic interference with other devices	EMC testing and electrical safety testing	IEC 60601-1:2005/AMD2:2020 IEC 60601-1-2:2014/AMD1:2020 IEC 60601-1-6:/AMD2:2020
	Labeling	ISO 15223-1 Fourth edition 2021-07 ISO 20417:2021, Corrected version 2021-12 IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION
	Non-clinical performance testing	Non-clinical performance data demonstrates that the device performs as intended under anticipated conditions of use. The following performance characteristics are tested i. Accuracy of needle penetration depth and puncture rate in pig skin with high - speed camera measurement;

Identified Risk to Health	**Mitigation Measures**	**Evidence**
		ii. Safety features built into the device to protect against cross-contamination, including fluid ingress protection due to a safety membrane; and iii. Identification of the maximum safe needle penetration depth for the device in pig skin with highspeed camera measurement.
Damage to underlying tissue including nerves and blood vessels, scarring and hyper and hypopigmentation. Exceeding safe penetration depth Mechanical failure Software malfunction	Technological characteristics	Non-clinical performance data demonstrates that the device performs as intended under anticipated conditions of use. The following performance characteristics are tested i. Accuracy of needle penetration depth and puncture rate in pig skin with high - speed camera measurement; ii. Safety features built into the device to protect against cross-contamination, including fluid ingress protection due to a safety membrane; and iii. Identification of the maximum safe needle penetration depth for the device in pig skin with highspeed camera measurement.
	Shelf life testing	ISO 11607-1 Second edition 2019-02 ISO 11607-2 Second edition 2019-02
	Labeling	ISO 15223-1 Fourth edition 2021-07 ISO 20417:2021, Corrected version 2021-12
	Software verification, validation and hazard analysis	IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION

8. Special Controls – Non clinical performance testing

In addition to the general standards and risk mitigation measures identified above, the Exceed Microneedling device has been subjected to the special controls outlined in 21 CFR 878.4430.

9. Clinical performance testing

Not applicable.

10. Statement of Substantial Equivalence:

513(i) of the FD&C Act (21 U.S.C. 360c(i) states that for substantial equivalence a proposed device is required to have the same intended use and similar technological characteristics as the predicate device. Where there are differences in technological characteristics, these can be negated by appropriate clinical or scientific data demonstrating that the proposed device is as safe and effective as the predicate device, and that the proposed device does not raise any different questions of safety and effectiveness than the predicate device for the same intended use.

MT.DERM GmbH has demonstrated that the Exceed Unlimited device has the same generic classification (generic description) and basic technologies as the predicate device Exceed microneedling system (K182407). Both devices are micro needling systems containing >1 needle that mechanically punctures or injures the skin for aesthetic use. Both devices have used needle depths of up to 1.5mm in clinical investigations.

Where there are differences between the Exceed Unlimited device and the predicate MT.DERM GmbH has conducted substantial non-clinical performance testing applicable to those general and special controls deemed necessary by the agency for this product classification and has determined that the Exceed Unlimited device raises no new questions relating to safety or efficacy and therefore has demonstrated that the Exceed Unlimited device is substantially equivalent to the referenced predicate K182407.