July 19, 2019

Mt. Derm GmbH
% Susan D'Arcy
Director
Ismart Marketing Svcs
129 Green Lanes, Wylde Green
Birmingham, B735LT Gb

Re: K182407
Trade/Device Name: Exceed Microneedling device
Regulation Number: 21 CFR 878.4430
Regulation Name: Microneedling Device For Aesthetic Use
Regulatory Class: Class II
Product Code: QAI
Dated: July 7, 2019
Received: July 9, 2019

Dear Susan D'Arcy:

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,

Cynthia Chang, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182407

Device Name
Exceed Microneedling device

Indications for Use *(Describe)*
The Exceed 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92(c).

Date Prepared: August 22nd 2018

Date amended: July 01th 2019

Submitter's Name: MT.DERM GmbH

Submitter's Address: Gustav-Krone-Str. 3, 14167 Berlin, Germany

Submitter's telephone number: +49 30 845 885 171

Contact Person: Andreas Pachten, Director QM and Regulatory Affairs

Device Trade Name: Exceed Microneedling device

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 micro needling 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 micro needling device consists of 7 component parts; Control Unit, Sterile single use Safety needle cartridge, Handpiece, Handpiece holder, Handpiece cover, Footswitch, Power supply.

The control unit switches the device on and off and contains the power source (5.5-12 V, DC (150mA)). The control unit adjusts the frequency of the needle stroke from 100-150Hz using a digital display and a keypad. The control unit receives power via a coaxial connector from a standard 100-240V, 50-60Hz, 1.2A wall socket transformer with an output of 15V. The handpiece contains a motor that moves the needles and a needle protrusion gauge that allows the user to control the depth of the needle protrusion from 0 - 1.9mm. The handpiece contains a scale that allows for the needle protrusion depth to be adjusted by the operator. The scale has a tolerance of ±0.15 mm. The standard safety needle cartridge is

a 6-stainless steel micro needle plate of 1.5 mm length. The safety needle cartridge is screwed into the handpiece. The safety needle cartridge is sterile and for single use only. This standard safety needle cartridge is used for Microneedling only. The length of needles is 1.5 mm. In combination with the handpiece needle protrusion can be adjusted between 0.0 mm (min) and a maximum of 1.5 mm .

3. Indications/Intended Use

The Exceed 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 prescription use device and complies with 21CFR 801.109.

4. Predicate Device

DEN160029 SkinPen Precision Microneedling system

SkinPen® Precision System DEN160029 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.

The Exceed Micro needling device is predicated against the SkinPen Precision microneedling system because both systems are microneedling devices containing one or more needles to mechanically puncture and injure the skin tissue for aesthetic use.

5. Technological Characteristics

Property	Exceed Microneedling device	DEN160029 SkinPen Precision Microneedling system	Significant differences
Device Manufacturer	MT.DERM GmbH Gustav-Krone-Str. 3, 14167 Berlin, Germany	Bellus Medical, LLC, 4505 Excel Parkway, Suite 100, Addison, TX 75001	Not applicable
Device Trade Name	Exceed Microneedling device	SkinPen Precision System	Not applicable
510(K) Number	K182407	DEN160029	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 use	Prescription use	Identical
Intended Location of Use	Face	Face	Identical
Intended use and Indications	The Exceed 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.”	SkinPen® Precision 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 or older.	Substantially Equivalent

Property	Exceed Microneedling device	DEN160029 SkinPen Precision Microneedling system	Significant differences
Geometry	6 needles, squared arrangement	14 needles, radial arrangement	Dissimiliar. Clinical and Non-clinical performance testing demonstrates that the Exceed microneedling device does not pose any undue or additional risks.
Needle protrusion setting	0 - 1.9 mm	0 - 2.5 mm	Dissimilar in general, but maximum needle penetration within the face for both devices is 1.5mm. Clinical and Non-clinical performance testing demonstrates that the Exceed microneedling device does not pose any undue or additional risks.
Maximum needle penetration (maximum needle length)	1.5mm	1.5 mm	Substantially equivalent. Both devices use a maximum needle penetration length of 1.5mm for the indication of treating acne scars (Skinpen references a capability of extending from 1.5mm to a maximum of 2.5mm however this has not been demonstrated to be safe and effective for this indication [Manufacturers claim[1]].
Frequency	100-150 Hz (±10%)	6300RPM to 7700 RPM[1] (105 – 128.3 Hz)	Dissimilar. Clinical and Non-clinical performance testing demonstrates that the Exceed microneedling device does not pose any undue or additional risks.

1 Data obtained from marketing material and user guide

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. Intended for prescription use.
iv. Location of use (Face)
v. The depth of penetration of the needles (needle length) is equivalent – 1.5mm

6.2. Differences.

Although the systems share the basic generic description and technologies they do differ in several areas.

a. Geometry and needle count
b. Needle protrusion setting

c. Frequency

These differences have been addressed by the manufacturer through the applicable safety standards (General controls and mitigation measures) and through clinical and non-clinical performance testing (Special controls).

a. **Geometry and needle count** – the difference in needle count and geometry has been addressed in terms of safety through specific non-clinical performance testing demonstrating that the needle geometry of the proposed device is uniform and clinical performance testing to demonstrate substantial equivalence. The difference in geometry and needle count does not raise any new questions in relation to safety or effectiveness compared to the predicate device.

b. **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 1.5mm in its reported clinical study and Instructions for Use and therefore is comparable to the proposed device that does not exceed 1.5mm. Non- Clinical performance testing demonstrates the needle protrusion setting of the proposed device is reproduceable within the technical specifications of the device. Clinical performance testing demonstrates safety and effectiveness in use.

c. **Frequency** – the frequency range (oscillation) of the Exceed microneedling device is greater than the predicate device. In terms of performance testing the upper range of 150 Hz was considered to be worst case scenario and therefore relevant non-clinical performance testing has been carried out at this maximum setting. Results from these range of tests provides evidence that this difference does not raise any new concerns regards safe use of the device in its intended use. Clinical performance testing demonstrates safety and effectiveness in use.

Although there are differences between the proposed device and predicate device DEN160029 SkinPen Precision System where there are differences, General controls of the FD&C Act and “Special controls” including non-clinical and clinical performance testing demonstrate that the Exceed microneedling device raises no new questions in relation to safety and effectiveness compared to the predicate device.

7. General controls and mitigation measures

To demonstrate safe and effective performance and support substantial equivalence the Exceed Microneedling device system 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 – 5,2009 10993-7:2008, 10993-10:2010 and ISO 10993-11:2017(E) and USP 40 <151> Pyrogen Test, 2017 and 10993-12:2012 FDA - Blue Book Memorandum #G95-1
	Labeling	ISO 15223-1:2012 EN 1041:2008 IEC 82079-1:2012 IEC62366:2007
Cross contamination and infection	Sterilization validation	ISO11135-1:2007 ISO/TS11135-2:2008 ISO11737-1:2006
	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 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 11607-1:2006+A1:2014 and ISO11607-2:2006+A1:2014
	Labeling	ISO 15223-1:2012 EN 1041:2008 IEC 82079-1:2012 IEC62366:2007

Identified Risk to Health	Mitigation Measures	Evidence
Electrical shock or Electromagnetic interference with other devices	EMC testing and electrical safety testing	IEC60601-1:2005 IEC60601-1-2:2014 IEC60601-1-6:2010
	Labeling	ISO 15223-1:2012 EN 1041:2008 IEC 82079-1:2012 IEC62366:2007
Damage to underlying tissue including nerves and blood vessels, scarring and hyper and hypopigmentation. Exceeding safe penetration depth Mechanical failure Software malfunction	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 iii. Identification of the maximum safe needle penetration depth for the device in pig skin with highspeed camera measurement.
	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_1:2006 ISO11607_2:2006
	Labeling	ISO 15223-1:2012 EN 1041:2008 IEC 82079-1:2012 IEC62366:2007
	Software verification, validation and hazard analysis	IEC62304:2006

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

A clinical study was conducted to support the safe and effective performance of the Exceed Microneedling device for the treatment of acne scars on the face.

The study was conducted at a single center. 56 otherwise healthy volunteers with facial acne scarring were recruited. Subjects underwent 4 micro needling sessions 4 weeks apart. Treatments were conducted by a medical physician.

Subjects were assessed at baseline and 12 weeks after the last treatment.

The subjects face was cleansed using a skin disinfecting product and numbed using a topical anaesthetic prior to the treatment. A sterile gel was applied to the subject's face to prevent abrasion and friction during the treatment. The physician was instructed to start with a minimum needle protrusion of 0.5 mm and increase until pinpoint bleeding was achieved. During the treatment blood was wiped away with a sterile saline solution, to prevent encrustation.

Forty-seven subjects (83.9%, (47/56)) completed all treatment and follow up visits.

The mean age of the subjects was 35.8 years (range 18-62 years). The study population was comprised of 18 (32.1%) males and 38 (67.9%) females. Fitzpatrick phototypes ranged from I -IV. No subjects with Fitzpatrick skin type V or VI were included in the study.

A summary of the subject demographics is given in Table 1.

Table 1: Subject demographics at baseline.

All Subjects		
N	**56**	
Age (years)		
Mean (SD)	**35.8 (9.9)**	
Minimum	**18**	
Median	**32**	
Maximum	**62**	
	N	**(%)**

Sex		
Male	**18**	**32.1**
Female	**38**	**67.9**
Fitzpatrick Skin Type		
I	**1**	**1.8**
II	**29**	**51.8**
III	**20**	**30.8**
IV	**6**	**10.7**
Acne Scar Assessment Scale		
Very mild (1)	**5**	**9**
Mild (2)	**14**	**25**
Moderate (3)	**21**	**37**
Severe (4)	**16**	**29**

Measurement of effectiveness

Physician measurement of effectiveness

At each visit digital photographs (VISIA) were taken of the subject's face. At the end of the study the digital images of the subject's face were randomized and analyzed independently by 3 physicians using the Acne Scar Assessment Scale (ASAS). The ASAS scale is a validated 5-point photo numeric descriptive grading scale used to grade acne scarring (table 2).

Table 2. Acne Scar Assessment Scale

Grade	Term	Description
0	Clear	No depressions are seen in the treatment area. Macular discoloration may be seen.
1	Very Mild	A single depression is easily noticeable with direct lighting (deep). Most or all of the depressions seen are only readily apparent with tangential lighting (shallow).
2	Mild	A few to several, but less than half of all the depressions are easily noticeable with direct lighting (deep). Most of the depressions seen are only readily apparent with tangential lighting (shallow).

Grade	Term	Description
3	Moderate	More than half of the depressions are apparent with direct lighting (deep).
4	Severe	All or almost all the lesions can be seen with direct lighting (deep).

Subject measurement of effectiveness

At the end of the study period subjects were asked to grade the effectiveness of the treatment using the following subject reported measures.

1. Self-assessed Scar Improvement Scale (SASIS)
2. Subject Global Aesthetic Improvement Scale (SGAIS)
3. Subject Satisfaction of treatment.

Measurement of Safety

During the study the physician recorded adverse events.

Using a subject diary, subjects graded their pain, discomfort and redness/swelling on the day of the treatment and thereafter daily until day 7. Pain and discomfort were recorded using an 11-point visual analogue scale (0-10) where 0 was equivalent to “no pain” or “no discomfort” to 10, “most intense pain ever” and “most discomfort ever”. A descriptive grading scale was used for subjects to evaluate their skin redness with the addition of photography depicting grades of skin redness in different phototypes (table 3).

Table 3 Redness grading scale

Grade	Description
None	No erythema or redness. Skin is normal color.
Minor	Very faint erythema or redness. Skin has a slight redness to it.
Mild	Blotchy, visible redness that does not cover the entire face. Skin has a noticeable inconsistent redness to it.
Moderate	Dull red color to the skin. Skin has a very definite redness to it.
Severe	Bright or dark red color to the skin. Skin is severely red.

Results – Safety

Physician recorded adverse events

No serious adverse events were reported. No adverse events persisted at the final follow up. In 18 out of 56 subjects (32%), 26 adverse events were reported during the study (Table 4).

There were 22 anticipated or expected adverse events and 4 unanticipated or unexpected adverse events. Three of the unexpected adverse events were attributable to the device (headache (n=2) and bleeding of treatment area 2 days post intervention (n=1). One unexpected event (fever and rigors) was not attributable to the device.

Of the 26 reported events, 23 of 26 (88.5%) were recorded as mild, and 3 of 26 (11.5%) as moderate. All but one event (Fever and ague, 1 of 26 (3.8%)) was attributable to the test device. No adverse event was directly linked or resulted in study discontinuation.
Bruising (6 events in 5 subjects) and swollen lymph-nodes (6 events in 3 subjects) were the most common adverse events. Table 4 lists all adverse events.

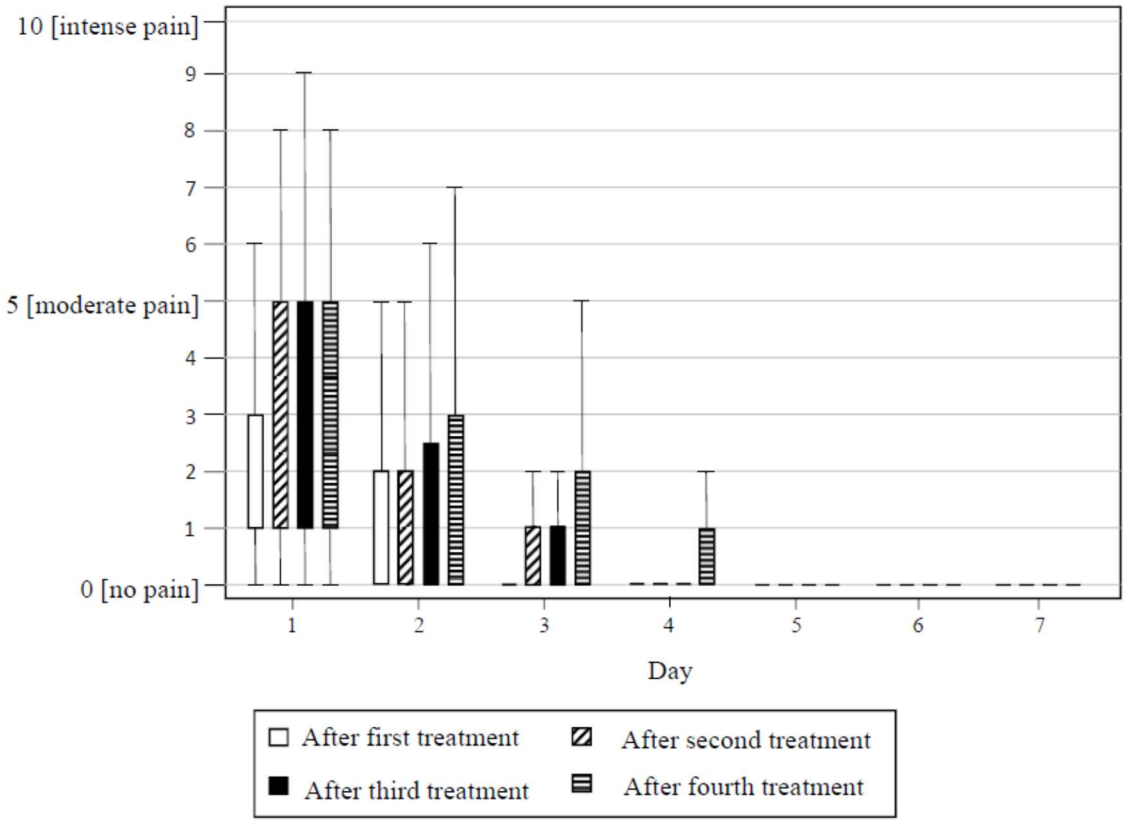
Table 4 – Adverse events

Adverse Event (AE) Category	Number of Adverse events	Number of subjects	Adverse events in relation to the device		Expected/ Unexpected	Fitzpatrick skintype
			Related	Non-Related		
Bleeding 2 days post treatment	1	1	1 (100%)	0	Unexpected	FP III
Bruising	6	5	6 (100%)	0	Expected	4/5 FP II 1/5 FP III
Fever and ague	1	1	0	1 (100%)	Unexpected	FP III
Flaking of the skin surface	3	1	3 (100%)	0	Expected	FP II
Headache	2	2	2 (100%)	0 0	Unexpected	1/2 FP II 1/2 FP III
Herpes simplex	1	1	1 (100%)	0	Expected	FP III
Hyperpigmentation	4	4	4 (100%)	0	Expected	1/4 FP II 2/4 FP III 1/4 FP IV
Pustules and rash	1	1	1 (100%)	0	Expected	FP III
Serous fluid leakage	1	1	1 (100%)	0	Expected	FP II
Swollen lymph nodes	6	3	6 (100%)	0	Expected	1/3 FP II 2/3 FP III
All categories	**26**	**18**	**25 (96%)**	**1 (4%)**	**-**	**-**

Subject reported outcomes - Pain and Discomfort

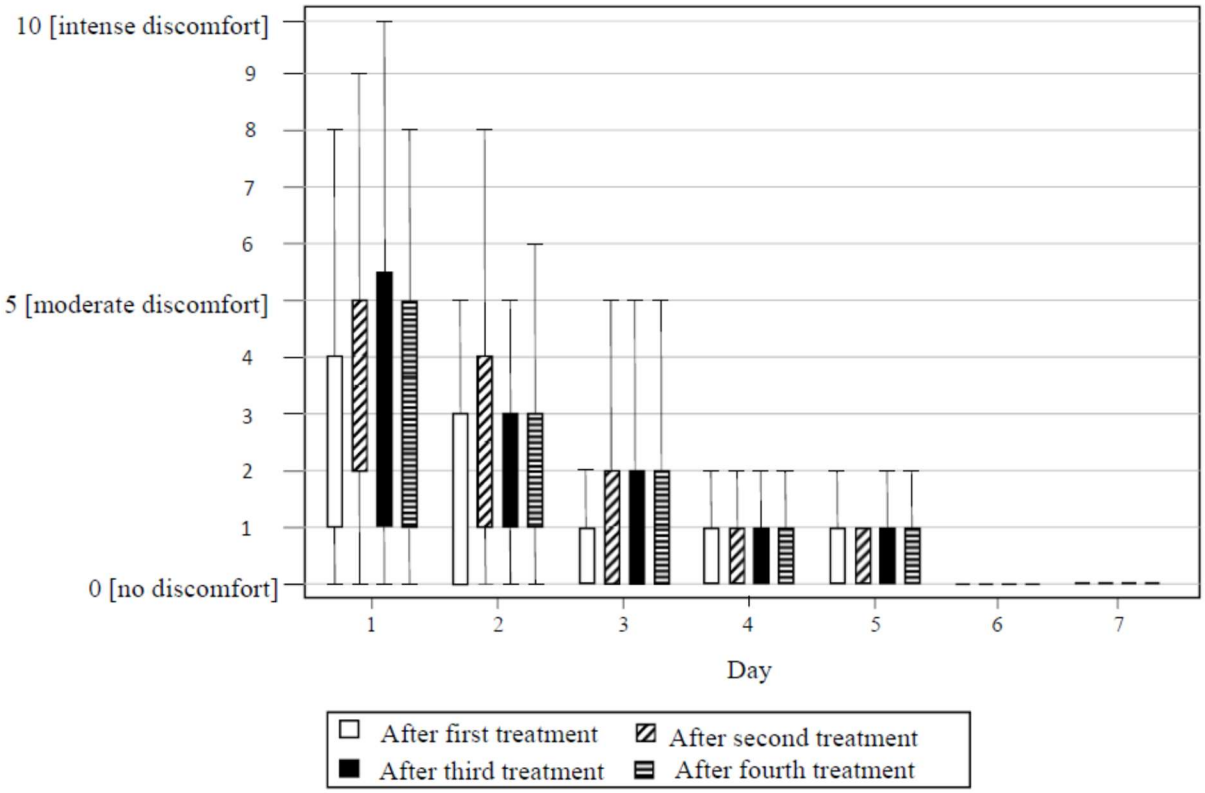
Subject evaluation of pain on the evening of the treatment showed a mean pain score of 2.8 (mean of 4 treatments, (range 0-9)). Mean pain scores receded to <1 by day 3 and receded further to 0.05 by Day 7. Discomfort was highest on Day 1 with a mean score of 3.20 across the 4 treatments, range 0-10. Discomfort had receded to <1 by day 4 and receded further to 0.12 by Day 7 (figure 1-2).

Figure 1. Subject recorded pain scores over 4 treatments[1]



1. based on a scale 0-10 0 = No pain. 10 = Worst pain ever

Figure 2. Subject recorded discomfort scores over 4 treatments[2]

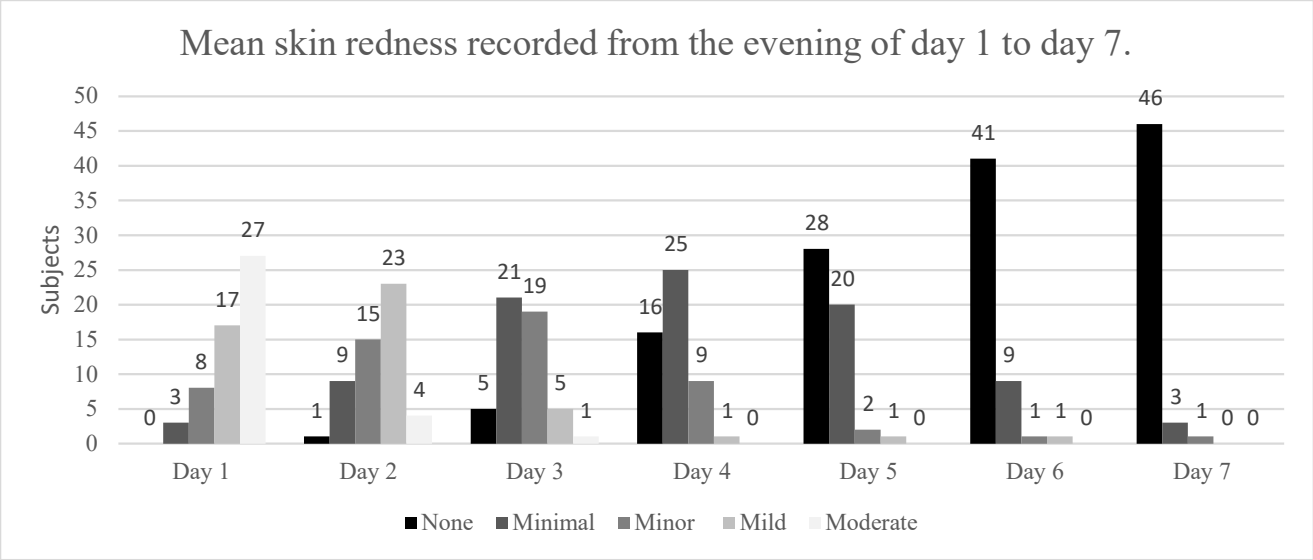


2. based on a scale 0-10 0 = No discomfort. 10 = Worst discomfort ever

Subject reported outcomes - Redness

27 of 55 subjects (49%) reported their skin to be moderately red on the evening of the treatment, the remainder reporting their signs to be mild or less than mild. By day 5, 48 of 51 subjects (94%) reported their skin redness as either minimal or absent (figure 3).

Figure 3. Subject recorded skin redness recorded from the evening of day 1 to day 7



Results – Effectiveness

Physician measurement of effectiveness

Results of the photograding using the Acne Scar Assessment Scale (ASAS) demonstrated that at baseline the mean population score was 2.89. At final follow up (3 months after the last treatment) the mean grade was 2.27 (table 5).

10/56 (18%) subject could not be evaluated by the 3 blinded physicians at final follow up, 3 months after last treatment. The reasons that 10 subjects could not be evaluated are listed below;

- 6 subjects did not complete all 4 treatments
- 3 subjects did not appear at the final follow-up
- 1 subject had no photographs at final follow-up

Table 5. Results of photograding of Acne Scar Assessment Scale from 3 blinded physicians

Timepoint	n	Mean	Standard Deviation	Minimum	Median	Maximum
Baseline	56	2.89	0.96	1	3	4
Final follow up 3 months after the last treatment	46	2.27	1.03	1	3	4

Treatment success was defined as subjects who improved by 1 grade as agreed upon by two out of 3 blinded physicians. A 1 grade improvement was seen in 27/46 (59%) of subjects. The evaluation by the three blinded physicians indicated that 38/46 (83%) of subjects showed an improvement greater than 0 but less than 1 in their acne scars according to the ASAS scale. 8/46 (17%) demonstrated no improvement from baseline. No subject's acne scars worsened over the study period (table 6).

Table 6. Change from Baseline of photograding of ASAS

Timepoint	n	Subjects improved 1 grade as agreed upon by 2 of 3 blinded physicians	Subject showed some improvement (improvement is greater than 0 but less than 1)	NO improvement	Subject worsened	Mean change	Standard deviation	Range
Final follow up 3 months post treatment	46	27 (59%)	38(83%)	8(17%)	0	0.59	0.38	0-1

Of the 38 subjects that showed some improvement; 20/24(83%) subjects were Fitzpatrick skin type II, 14/18(78%) were Fitzpatrick skin type III and 4/4(100%) were Fitzpatrick skin type IV

Of the 17 subjects that improved by 1 grade; 8/24(33%) subjects were Fitzpatrick skin type II, 5/18 (28%) were Fitzpatrick skin type III and 4/4(100%) were Fitzpatrick skin type IV.

Results – Effectiveness - Subject measurement of effectiveness

Self-assessed Scar Improvement Scale (SASIS)

Subjects assessed their acne scarring compared to baseline using the Self-assessed Scar Improvement Scale (SASIS). Thirty-eight, 38/43 (88%) of subjects reported some improvement in their acne scarring. Five subjects 5/43 (12%) reported no improvement. No subjects reported a worsening of their acne scars (table 7).

Table 7. Self-assessed Scar Improvement Scale (SASIS)

Self-assessed Scar Improvement Scale (SASIS)	**Compared to the beginning of the study please rate your facial scars now?**					
Grading	- 1 Exacerbation of Acne Scars	0 No change in appearance of my acne scars	1 1% - 25% improvement in appearance of my acne scars	2 25% - 50% improvement in appearance of my acne scars	3 50% - 75% improvement in appearance of my acne scars	4 75% - 99% improvement in appearance of my acne scars
Number of Subjects (n=43)	0	5	18	15	4	1
% of Subjects	0.0	11.6	41.9	34.9	9.3	2.3

Subject Global Aesthetic Improvement Scale (SGAIS)

Subjects also assessed their acne scarring compared to baseline using the Subject Global Aesthetic Improvement Scale (SGAIS). Thirty-three, 33/43 (77%) of subjects reported some improvement in their acne scarring. Ten subjects 10/43 (23%) reported that the appearance of their acne scarring was essentially the same as the original condition. No subjects reported that the appearance of their acne scars worsened (table 8).

Table 8. Subject Global Aesthetic Improvement Scale (SGAIS)

Subject Global Aesthetic Improvement Scale	**Compared to the beginning of the study please rate your facial scars now?**				
Grading	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.
Number of Subjects (n=43)	0	4	29	10	0
% of Subjects	0.0	9.3	67.4	23.3	0.0

Additional questions of subject's satisfaction

1. **Do you notice any improvement in how your acne scars look in the treated area?**

Yes [N, (%)]	No [N, %]
37 (86%)	6 (14%)

2. **How would you characterize your satisfaction with the treatment**?

How would you characterize your satisfaction with the treatment?							
Grading	**Extremely satisfied**	**Satisfied**	**Slightly satisfied**	**Neither satisfied nor dissatisfied**	**Slightly dissatisfied**	**Dissatisfied**	**Extremely dissatisfied**
Number of Subjects (n=-43)	7	18	10	7	0	1	0
% of Subjects	16.3	41.9	23.3	16.3	0.0	2.3	0.0

3. **Would you recommend this treatment to your friends and family members?**

Yes [N, %]	No [N, %]
38 (88%)	5 (12%)

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 Microneedling device has the same generic classification (generic description) and basic technologies as the predicate device DEN160029. 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 micro needling device and the predicate (DEN160029) MT.DERM GmbH has conducted clinical and 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 microneedling device raises no new questions relating to safety or effectiveness and therefore has demonstrated that the Exceed microneedling device is substantially equivalent to the referenced predicate DEN160029.