December 20, 2022

Equipmed USA LLC
Shaun Kerrigan
VP of Legal and Regulatory Affairs
Suite 1100, 4695 Macarthur Court
Newport Beach, California 92660

Re: K221070
Trade/Device Name: DP4 Microneedling device
Regulation Number: 21 CFR 878.4430
Regulation Name: Microneedling Device For Aesthetic Use
Regulatory Class: Class II
Product Code: QAI
Dated: November 14, 2022
Received: November 21, 2022

Dear Shaun Kerrigan:

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,

Colin K. Chen -S

for

Long Chen, Ph.D.
Acting Director
DHT4A: Division of General 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)*
K221070

Device Name
DP4 Microneedling device

Indications for Use *(Describe)*
The DP4 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, IV and V 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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510k Summary

Date Prepared: December 19th, 2022

Submitter's Company Name: EQUIPMED USA LLC

Submitter's Address: EQUIPMED USA LLC, Suite 1100, 4695 Macarthur Court, Newport Beach, CAL 92660

Contact person: Shaun Kerrigan

Telephone: +1 949 798 6111

Device Trade Name: DP4™ 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 micro needling 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

DP4 Microneedling device is a Digital Automated Microneedling system. The DP4 system consists of the following components:

1. Handpiece
2. Needle Cartridge
3. DP4 Sleeve (barrier sleeve)
4. Battery Charger, 2 Batteries
5. AC/DC Power Adaptor
6. Desk Stand
7. DP4 US™ companion app.

The handpiece (1) contains a mains connector, a drive train, a digital display to relay information to the operator an ON/OFF button and 2 separate toggle buttons to adjust frequency and needle depth.

The handpiece receives its power via an external AC/DC power adaptor (input Voltage/Current is 100-240VAC, 1.0–0.5A,50–60Hz: Output Voltage/Current: 5V DC, 2.4A) or removable lithium ion battery (3.7 VDC). The battery does not need to be removed to make use of the mains power adaptor. The power adaptor connects to the handpiece via a custom DC connection (over-mold bayonet type).

The drive train encompasses a DC motor, eccentric cam and rotational to linear drive converter to oscillate the Cartridge needles.

The digital display shows battery status, cartridge status, sync/update notifications and bluetooth connectivity. The display also contains a digital dial to convey frequency or motor speed and a 3-figure display showing current needle depth.

The frequency of oscillation can be set from 80-110Hz (+/-10 Hz(range 70-120Hz) and the needle depth from 0.2mm to 3mm.

The DP4 needle Cartridge (2) is a sterile, single use consumable designed to create micro incisions in the epidermis and dermis. Each cartridge contains 16, 3mm, 33-gauge surgical grade stainless steel needles, arranged in a circular pattern. Each needle cartridge employs a bayonet feature to securely connect it to the handpiece during operation. Internal and external seals assist in the prevention of cross contamination. Each needle Cartridge contains a Radio-frequency identification (RFID) tag encoded with a unique ID and a needle depth correction factor. This information is read from the cartridge when it is first inserted into the handpiece and prevents reuse of the cartridge once the cartridge is removed from the handpiece.

The DP4 sleeve (3) is a single use, sterile, biohazard barrier used to prevent contamination of the handpiece by bodily fluids generated during the treatment. It covers the extent of the handpiece, including the intersection between the handpiece and needle Cartridge.

The battery charger (4) is capable of charging 1 x 14500 Lithium cell. The system batteries can only be charged when removed from the handpiece and inserted into the battery charger.

The desk stand (5) is used for storage of device while not in use.

The DP4 US companion app software application (6) is an app. run on a Bluetooth enabled User device to enable the User to interact with the DP4 CRM system. The app contains no patient data and transmits no patient data. The equipment is not used to make measurements of any sort, or to draw any conclusions regarding the indication to treat.

3. Indications for Use

The DP4 microneedling device is a micro needling 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, IV and V in adults aged 22 years or older.

The DP4 is a prescriptive device intended to be used by physicians and suitably qualified personnel. and complies with 21CFR 801.109

4. Predicate Device

DEN160029 SkinPen Precision Micro needling 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 DP4 microneedling device is predicated against the SkinPen Precision micro needling system because both systems are micro needling devices containing one or more needles to mechanically puncture and injure the skin tissue for aesthetic use.

5. Substantial Equivalence information:

The DP4 microneedling device is predicated against the SkinPen Precision micro needling system because both systems are micro needling devices containing one or more needles to mechanically puncture and injure the skin tissue for aesthetic use.

Property	DEN160029 SkinPen Precision Microneedling system	DP4 Microneedling device	Significant differences
Device Manufacturer	Bellus Medical, LLC, 4505 Excel Parkway, Suite 100, Addison, TX 75001	Equipmed USA LLC Suite 1100, 4695 Macarthur Ct Newport Beach, CA 92660	Not applicable
Device Trade Name	SkinPen Precision System	DP4 Microneedling device	Not applicable
510(K) Number	DEN160029	K221070	Not applicable
Device Classification name	Micro needling device for aesthetic use	Micro needling device for aesthetic use	Identical

Property	DEN160029 SkinPen Precision Microneedling system	DP4 Microneedling device	Significant differences
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	Prescriptive	Prescriptive	Identical
Intended Location of Use	Face	Face	Identical
Intended use and Indications	SkinPen® Precision System is a micro needling 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 DP4™ 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, IV and V in adults aged 22 years or older.	Identical save restriction by labelling of Fitzpatrick skin types.
Geometry	14 needles (radial arrangement)	16 needles (radial arrangement)	Similar
Needle protrusion setting	0 - <2.7 mm[1]	0.2mm – 3mm	Similar
Maximum needle length	2.5 mm	3mm	Different
Maximum needle penetration in clinical application	1.5 mm	2.5mm	Different
Frequency	105 – 128.3 Hz	80-110Hz (+/- 10 Hz)	Substantially equivalent

Property	DEN160029 SkinPen Precision Microneedling system	DP4 Microneedling device	Significant differences
Treatment protocol	3 treatments spaced 4 weeks apart	3 treatments spaced 4 weeks apart	Identical

6. Substantial Equivalency and Comparison of Technological Similarities & Differences

6.1. Key Similarities.

i. The DP4 has the same intended use as the Skinpen Precision microneedling device, 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 DP4 is restricted to Fitzpatrick skintypes I through V. Evidence for this is provided in clinical performance data.
ii. 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.
iii. Both devices use a needle cartridge with stainless steel needles in a circular formation. The sponsor has provided suitable drawings and testing to demonstrate suitable assurances of equivalence and Biocompatibility to standards recommended by the agency. Clinical performance testing demonstrated no additional concerns in terms of unanticipated side effects in relation to needle configuration.
iv. Both systems are intended for prescriptive use and both have identical treatment protocols
v. The frequency of oscillation of the proposed device is within the tolerance of the predicate device and does not exceed the upper frequency of the predicate device, previously cleared by the agency. The predicate device has a maximum frequency of 128.3 Hz. The proposed device even at its upper tolerance is within this range (120Hz (Acceptable range 70 – 120Hz)). Clinical performance testing demonstrated no additional concerns in terms of unanticipated side effects in relation to frequency.

6.2. Differences.

i. The systems share the basic generic description and critical technologies but differs in the maximum needle depth used in a clinical setting. The predicate device states a maximum needle penetration depth as 2.75+/- 0.35mm, therefore giving it an upper range of 2.4-3.1mm. The proposed device was tested to demonstrate that at the maximum selectable depth of the device, the needle extension does not go beyond the expected maximum needle penetration depth (3mm). The results showed needle extension slightly below the maximum selectable depth but within specification illustrating that at the most extreme extension the needles remain within specification. Nonclinical performance testing also demonstrated that the operator setting of needle penetration depth on the DP4 handpiece correlates with the actual depth that the needle penetrates the skin and is within tolerances predefined by the manufacturer +0.05mm / -0.4mm. The purpose of this test is not to compare per se with the predicate but to demonstrate that as per the agency's guidelines on micro needling devices that the technical specifications and needle characteristics have been identified, including maximum penetration depth.
ii. The maximum permissible depth of penetration of the needles used in the clinical study for the proposed device was 2.5mm with an average of 2.3mm and 2.0mm versus 1.5mm

for the predicate device. Clinical performance testing demonstrated no additional concerns in terms of unanticipated side effects in relation to the penetration depth of the proposed device. The predicate device can extend beyond 1.5mm, however the predicate device is restricted by labelling alone and this is true for all current products cleared under the QAI code (DEN160029).

The technological characteristics of the proposed device have been addressed by the manufacturer through the applicable safety standards (General controls and mitigation measures) and clinical and non-clinical performance testing.

7. General controls and mitigation measures

To demonstrate safety and effectiveness and support substantial equivalence the DP4 Microneedling device has undergone several 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.

IEC 60601-1: 2005/AMD1:2012. Medical electrical equipment Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014 (ed. 4.0) Includes CFR47 FCC Part 15, Subpart B Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
IEC 62304: 2006 (ed. 1.0) Medical Device Software - Software Life Cycle Processes
ISO 10993-5: 2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.
ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity and pyrogens.
ISO 11607-1: 2006 + Amd 1: 2014 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems. (inc amendment 2014).
ISO 11607-2: 2006 + Amd 1:2014 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes. (inc amendment 2014).
ANSI/AAMI/ISO 11135:2014 Sterilization of Health Care Products - Ethylene Oxide - Requirements For Development, Validation And Routine Control Of A Sterilization Process For Medical Devices.

ISO/TS 11135-2: 2008 Sterilization of health care products - Ethylene oxide - Part 2: Guidance on the application of ISO 11135-1
ISO 11737-1:2009 Sterilization of medical devices – Microbiological methods – Part 1 : Determination of a population of microorganisms on products
ISO 11737-2:2009 Sterilization of medical devices – Microbiological methods – Part 2 : Tests of sterility performed in the validation of a sterilization process
ASTM F1671/F1671M-13 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

9. Other non-clinical performance testing

In addition to the general standards and risk mitigation measures identified above the DP4 Microneedling device has been subjected to several non-clinical safety tests to include.

i. The technical specifications and needle characteristics have been identified, including needle length, geometry and maximum penetration depth
   The following performance characteristics have been tested:
   i. Accuracy of needle penetration depth in porcine skin
   ii. Safety features built into the device to protect against cross-contamination, including fluid ingress protection due to a safety membrane and prevention of needle re use using RFID tags
ii. A cleaning validation was performed for reusable components of the device.
iii. Suitable labelling has been provided to allow safe and effective use of the device to include.
   a. Information on how to operate the device and its components and the typical course of treatment.
   b. A summary of the device technical parameters, including needle length, needle geometry, maximum penetration depth, and frequency.
   c. Validated methods and instructions for reprocessing of any reusable components.
   d. Disposal instructions.
   e. Maximum Shelf life.
   f. Patient labeling included:
      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.

10. Clinical performance testing

Two clinical studies were undertaken to assess the safety and effectiveness of the DP4 micro needling device in reducing scarring of atrophic acne scars.
Both studies were independent from each other.

Study #1

The Primary effectiveness endpoint of the study was to show a reduction in acne scarring in accordance with the Acne Scar Assessment Scale as used by Skinpen (Bellus Medical (DEN160029)).
The safety endpoint of the study was the incidence of adverse events and side effects.
The study was a single center involving 22 healthy patients.
Each patient underwent two micro needling sessions, four weeks apart, using the DP4 micro needling device and individual sterile micro needling cartridges. Patients were assessed at baseline and at week 8. If the assessing physician deemed a third treatment was necessary, the patient underwent an additional treatment and was assessed 4 weeks after the 3rd micro needling treatment.
Before treatment, the face was cleansed to remove all makeup and a numbing cream containing a local anesthetic was applied to the skin. After incubation, the numbing cream was removed from the patient's face.
The operator began treatment using a minimum depth of 1mm and a frequency setting of 4 (corresponding to 120 Hz). Needle depth and frequency was adjusted until pin-point bleeding occurred.

Measurement of Safety and Effectiveness

Adverse events (side effects) were recorded during the duration of the study period. Patient-assessed pain and physician-assessed erythema were also recorded immediately after treatment. Patient documented side effects (redness, pain, and discomfort) and patient observations using a patient diary, commencing on the evening of the treatment for 7 days.
Acne scarring was recorded photographically at baseline (i.e. before first session) and at final assessment (i.e. four weeks after the last micro needling session). The scarring was assessed retrospectively from a randomized set of images by independent blinded physicians using the Acne Scar Assessment Scale (ASAS).Success was measured as the number of patients seeing a 1-point improvement on the validated ASAS scale from baseline to 4 weeks after the second treatment.

Patient demographics

Thirty-two patients were screened for suitability, twenty-two (n=22) were suitable and took part in the study. Of the 10 volunteers that were deemed unsuitable, five (5) were suffering from active acne vulgaris, two (2) subjects were suffering from melasma in the treatment area and three (3) were suffering from facial scars resulting from Varicella zoster.

Twenty-two (n=22) patients were enrolled into the study, twenty-two patients completed the required treatments. The mean age of the patient group was 38 years (range 23-55 years) and the group comprised 4(18%) males and 18 (82%) females. Fitzpatrick phototypes ranged from I to V (Average FP- III). Three patients identified as non-Hispanic, 19 identified as Hispanic. At baseline,

the mean global acne grading according to Goodman and Baron was 3, representing a moderate disease.
Eighteen patients underwent 2 treatments, four patients underwent 3 treatments. No patients dropped out during the study period. All patients attended their follow up visits.

Table i: Patient demographics.

All Patients			
N	**22**		
Age (years)			
Mean	**38**		
Minimum	**23**		
Maximum	**55**		
	N		**(%)**
Sex			
Male	**4**		**18%**
Female	**18**		**82%**
Fitzpatrick skin type			
I	**1**		**5%**
II	**6**		**27%**
III	**6**		**27%**
IV	**6**		**27%**
V	**3**		**14%**
Ethnicity			
Hispanic or Latino	**19**		**86%**
Non-Hispanic	**3**		**14%**
White	**21**		**95%**
Black	**1**		**5%**
Mean Goodman & Baron baseline grading	**Mean grade**	**Patients presenting**	**Range**
Global grade	**3**	**-**	**2-4**
Icepick	**1**	**10**	**0-4**
Rolling	**2**	**17**	**0-3**
Boxcar	**2**	**17**	**0-4**

Baseline grading of acne scarring using ASAS

Baseline grading of acne scarring using ASAS is given in table ii. The average grade across all evaluators was 3, equivalent to Moderate severity, >50% of acne scars visibly apparent with direct lighting. This average grade correlated with the Global grade using the Goodman and Baron grading scale.

Table ii. Number of patients presenting at baseline with acne scarring according to ASAS

Grade	Evaluator 1	Evaluator 2	Evaluator 3
0	0	0	0
1	0	0	0
2	8	6	6
3	10	13	13
4	4	3	3
Average grade	**2.8**	**2.9**	**2.9**

All patients completed all treatment and follow-up visits

Treatment parameters

The operator began treatment using a minimum depth of 1mm and a frequency setting of 4 (corresponding to 120 Hz). Needle depth and frequency was adjusted until pin-point bleeding occurred.

The lowest needle depth and frequency to achieve pinpoint bleeding was recorded as 1 mm and a speed setting of 4 (120Hz) The highest needle depth and speed setting to achieve pinpoint bleeding was recorded as 2.5mm and a speed setting of 4 (120Hz). The average minimum needle depth recorded over the treatment period was 1.3mm. The average maximum needle depth recorded over the treatment period was 2.3mm**.**

Results

Measurement of Safety

There were no reported adverse events other than those side effects reported by patients through their patient diary.

Immediately after the treatment, the investigating physician graded the amount of erythema in the treatment area. Erythema grading ranged from Mild to moderate across all 3 treatments. No patient's erythema was graded as severe.

The Mean pain score was recorded immediately after treatment by the patient. The highest mean pain score was 3.1 (range 0-7) immediately after the first treatment and then tapered slightly to 2.5 and 2.3, respectively for the second and third treatment. Patient evaluation of pain on the evening of day 1 showed a mean pain score of 1.5 (mean of 3 treatments, (range 0-7)) down by 1.6 from immediately after the treatment. Mean pain scores receded to <1 by day 2 (range 0-4) and receded further to <0.5 by Day 4 (range 0-4).

Erythema grading by the patient appeared to be consistent over the initial 2 treatments, with patients grading between minor erythema and moderate erythema. Only 1 patient graded their erythema as severe. On the evening of day 1, erythema ranged from minor to severe but reduced gradually over days 2-5. At day 6 no patients reported erythema.
Patient evaluation of discomfort on the evening of day 1 showed a mean score of 1.5 (range 0-8). Mean discomfort scores receded to <1 by day 4 (range 0-5).
Peeling occurred beginning of day 3, reaching a mean average on day 4 of 2.9 (range 0-10). By day 7, peeling had subsided and was graded as <1 (0-1)
Patients were asked to record skin dryness at home from the evening of the treatment to day 7. Skin dryness was not reported by most patients until day 3 (59-75%) and then subsided. By day 6 no patients reported dry skin.

Measurement of effectiveness

Effectiveness conclusions
For the Acne Scar Assessment Scale (ASAS) 17 of the 22 subjects (77%) had a 1-point improvement on the ASAS for blinded evaluators when comparing baseline to 4 weeks post-second treatment. The mean grading score across the 3 evaluators, 4 weeks after the second treatment was 1.4, representing a mean improvement from baseline of 1.5 of a grade.

Improvement in acne scarring
Tables iii and iv show the frequency distributions and mean values of the improvements in ASAS scores after two treatments and after three treatments. Also shown are the numbers and percentages of patients who had improved.

Table iii Summary of improvements in ASAS scores after two treatments

Improvement*	Patient	Evaluator 1	Evaluator 2	Evaluator 3
0	4	5	2	4
1	8	9	8	7
2	6	7	9	8
3	4	1	3	3
4	0	0	0	0
Total	**22**	**22**	**22**	**22**
Mean	1.5	1.2	1.6	1.5
95% CI	1.0, 1.9	0.8, 1.5	1.2, 1.9	1.1, 1.9
No. of +ves	18	17	20	18
% +ves	82	77	91	82
95% CI	60, 95	54, 92	71, 99	60, 95

* Baseline score minus follow-up score

Table iv Summary of improvements in ASAS scores after three treatments

Improvement*	Patient	Evaluator 1	Evaluator 2	Evaluator 3
0	0	0	0	0
1	0	0	2	1
2	3	4	1	2
3	1	0	1	1
4	0	0	0	0
Total	**4**	**4**	**4**	**4**
Mean	2.3	2.0	1.8	2.0
95% CI	1.8, 2.7	-	0.8, 2.7	1.2, 2.8
No. of +ves	4	4	4	4
% +ves	100	100	100	100
95% CI	48, 100	48, 100	48, 100	48, 100

For the two-treatment data, the lowest and highest percentages improved were seen for Evaluator 1 (77%) and Evaluator 2 (91%). Evaluator 3 gave the same improvement percentage as the patient self-assessments. No patient's acne scarring worsened.
All four patients having three treatments had improved.

Baseline average grading using Baron and Goodman was; Global, 3, Icepick, 1, Rolling, 2 and Boxcar, 2. 4 weeks after the final treatment the gradings were Global, 1.5, Icepick, 0.5, Rolling, 0.9 and Boxcar, 1. This translated to an improvement in terms of global grading of 1.5 of a grade and ≥1 grade improvement in Rolling and Boxcar. Only icepick failed to improve by ≥1 grade, however the author notes that only 10 patients presented with icepick scarring.
No patient's acne scarring worsened. All four patients who went on to have three treatments improved.

Patient reported outcomes
All patients reported that they noticed an improvement of their acne scars in the treatment area.
All patients apart from one (1/22(5%) stated that they would recommend the treatment to friends and family. When asked to characterize the treatment 18/22 (82%) were very satisfied with the treatment and 4/22 (18%) were moderately satisfied.
Patients were asked to grade their acne scarring 4 weeks after their last treatment in respect to percentage improvement. Eight (8/22 (36%) perceived a >75% improvement in acne scarring, compared to baseline. Thirteen (13/22(59%)) perceived a 50 -75% improvement in acne scarring compared to baseline and a single patient perceived a 25-50% improvement.
Twelve patients (12/22 (55%)) perceived that their acne scars had very much improved compared to their appearance at the beginning of the study. Eight (8/22(36%)) indicated that their acne

scarring had much improved from the original condition but had not completely cleared and two (2/22(9%) indicated that their acne scarring had improved).No patients perceived that their acne scarring had worsened.

Additional Clinical Performance data.

Study #2

An open label study was initially conducted by the sponsor to assess the safety and efficacy of the DP4 microneedling device. The study involved two centers and 20 healthy patients.

Each patient underwent three microneedling sessions, four weeks apart, using the DP4 microneedling device and individual sterile microneedling cartridges.

Before treatment, the face was cleansed to remove all makeup and a numbing cream containing a local anesthetic was applied to the skin. After incubation, the numbing cream was removed from the patient's face.

The operator began treatment using a minimum depth of 1mm and a frequency setting of 4 (corresponding to 120 Hz). Needle depth and frequency was adjusted until pin-point bleeding occurred.

Adverse events (side effects) were recorded during the duration of the study period. Patient-assessed pain and physician-assessed erythema were also recorded. No other patient reported outcomes were recorded.

Acne scarring was recorded photographically at baseline, before the first session and at final assessment, four weeks after the last microneedling session. The scarring was assessed retrospectively from the randomized set of images by two independent blinded physicians using the Acne Scar Assessment Scale (ASAS) and the Goodman and Baron acne scar grading scale.

Results

The mean age of the patient group was 39.9 years (range 21-67 years) and the group comprised 5 (25%) males and 15 (75%) females. Fitzpatrick phototypes ranged from II to IV.

The lowest needle depth and frequency to achieve pinpoint bleeding was recorded as 1 mm and a speed setting of 4 (120Hz) The highest needle depth and speed setting to achieve pinpoint bleeding was recorded as 2.5mm and a speed setting of 4 (120Hz). The average needle depth recorded over the treatment period was 2.0mm.

Measurement of Safety

There was a single reported adverse incident reported as excessive swelling in the treatment area over the first 48 hours after treatment. The swelling was self-limiting and had returned to normal within 96 hours. The mean value of the patient-assessed pain scores on the 11-point visual analogue scale (0-10) was 5.7 (range 4-7). Post-treatment erythema graded by the research staff ranged from mild to severe (mild: n=8; moderate: n=3; severe: n=9).

Measurement of effectiveness

Results of the photograding using the Acne Scar Assessment Scale demonstrated that at baseline the mean acne grading score was 2.58, corresponding to borderline 'mild'/'moderate'. At final follow-up the mean grade was 1.53, corresponding to borderline 'very mild'/'mild', a mean improvement of 1.06.

Physician K graded 14/20 (70%) as ≥ 1 improvement in acne scarring according to the ASAS grading and Physician E assessed 17/20 (85%) as ≥ 1 grade improvement.

No patient's acne scarring worsened over the study period

Of the 14/20 patients whose ASAS grade improved by ≥ 1 as assessed by Physician K, 6/9(67%) were Fitzpatrick skin type II, 7/9(78%) were Fitzpatrick skin type III and 1/2(50%) were Fitzpatrick skin type IV.
Of the 17/20 patients whose ASAS grade improved by ≥ 1 as assessed
by Physician E, 9/9(100%) were Fitzpatrick skin type II, 7/9(78%) were Fitzpatrick skin type III and 1/2(50%) were Fitzpatrick skin type IV.

11. 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.
Equipmed USA LLC has demonstrated that the DP4 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.
Where there are differences between the DP4 microneedling device and the predicate (DEN160029) Equipmed USA LLC 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 DP4 microneedling device raises no new questions relating to safety and therefore has demonstrated that the DP4 microneedling device is substantially equivalent to the referenced predicate DEN160029.