



February 19, 2026

Esthetic Medical Inc.
Sean Song
Manager Regulatory Affairs
3600 E Burnett St
Long Beach, California 90815

Re: K253002

Trade/Device Name: SkinStylus SteriLock® MicroSystem (MP1209SL)

Regulation Number: 21 CFR 878.4430

Regulation Name: Microneedling Device For Aesthetic Use

Regulatory Class: Class II

Product Code: QAI

Dated: January 16, 2026

Received: January 16, 2026

Dear Sean Song:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JODIE GIORDANO -S

Jodie Giordano, Ph.D.

Acting Assistant Director

DHT4B: Division of Plastic and

Reconstructive Surgery Devices

OHT4: Office of Surgical and

Infection Control Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K253002

Device Name
SkinStylus SteriLock® MicroSystem

Indications for Use (Describe)

The SkinStylus SteriLock® MicroSystem is a microneedling device and accessories intended to be used as a treatment to improve the appearance of periorbital wrinkles in Fitzpatrick skin types I, II, III, IV, V, and VI in adults aged 34 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

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

Submitter's Name:	Esthetic Medical Inc.
Submitter's Address:	3600 East Burnett Street, Long Beach, California 90815
Contact Person:	Sean Song
Telephone:	+1.509.413.6458
Date Prepared:	February 19, 2026
Device Trade Name:	SkinStylus SteriLock® MicroSystem
Common Name:	Powered microneedle device
Classification Name:	Microneedling device for aesthetic use
Regulation Number:	21 CFR 878.4430
Product Code:	QAI
Review Panel:	General & Plastic Surgery
Predicate Device:	K180778. Exceed Microneedling Device

Intended Use¹

The SkinStylus SteriLock® MicroSystem is intended to be used as a treatment to improve the appearance of surgical or traumatic hypertrophic scars on the abdomen in adults aged 22 years or older.

The SkinStylus SteriLock® MicroSystem 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, and III in patients aged 22 years and older.

The SkinStylus SteriLock® MicroSystem is a microneedling device and accessories intended to be used as a treatment to improve the appearance of periorbital wrinkles in Fitzpatrick skin types I, II, III, IV, V, and VI in adults aged 34 years or older.

Device Description

The SkinStylus SteriLock® MicroSystem (SSM) is a handheld microneedling device that uses an adjustable speed 5V 1A DC motor to rapidly reciprocate an array of 32-gauge microneedles that are no longer than 2.5 mm to create channels as well as microinjuries into the skin. The device consists of a power source, a motor body with depth adjustment, a removable nosecone interface, and a disposable, single-use, gamma ray sterilized cartridge, containing an array of microneedles.

¹ The SkinStylus SteriLock® MicroSystem is already cleared for abdominal scarring under K200044 and for facial acne scarring under K231073. Facial wrinkles is the only indication that is new or changed under this submission.

The SSM receives power from either a rechargeable lithium-ion battery or directly from an external AC/DC power adapter (input: 100-240 VAC/50-60 Hz, output: 5 VDC, 1 A).

Technical specifications, including needle characteristics

Characteristic	Specification
Needle geometry	36 solid needles arranged in a 6 × 6 square
Max needle length	2.5 mm
Needle protrusion setting	0.0 to 2.5 mm with marked 0.1 mm increments
Maximum needle penetration in clinical application	2.5 mm
Accuracy of needle penetration depth	± 0.25 mm
Reciprocation rate	6200 to 8840 RPM

Substantial Equivalence

The SkinStylus SteriLock® MicroSystem is substantially equivalent to the Exceed Microneedling Device (K180778), which is a prescription-only powered microneedling device indicated 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.

Substantial Equivalence

Description	Subject device SkinStylus SteriLock® MicroSystem	Predicate device Exceed Microneedling Device (K180778)	Significant differences
Manufacturer	Esthetic Medical Inc. 3600 E Burnett St Long Beach, CA 90815	MT.DERM Gustav-Krone-Str. 3, 14167 Berlin, Germany	N/A
Manufacturing location	Guangzhou Carain Beauty Equipment Guangzhou, China	Not specified in 510(k) summary	N/A
Device trade name	SkinStylus SteriLock® MicroSystem	Exceed Microneedling Device	N/A
510(k) number	-	K180778	N/A
Device classification name	Microneedling device for aesthetic use	Microneedling device for aesthetic use	Same
Device product code	QAI	QAI	Same
Regulation number	21 CFR 878.4430	21 CFR 878.4430	Same
FDA device classification	Class II (special controls)	Class II (special controls)	Same
Use	Prescription only	Prescription only	Same
Intended use and indications	<p>The SkinStylus SteriLock® MicroSystem is a microneedling device and accessories that are intended to be used for the following purposes:</p> <ul style="list-style-type: none"> As a treatment to improve the appearance of surgical or traumatic hypertrophic scars on the abdomen in adults aged 22 years or older. 	<p>The Exceed is a microneedling device and accessories is 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.</p>	<p>The subject device and Exceed are indicated for the treatment of certain types of facial wrinkles.</p>

Description	Subject device SkinStylus SteriLock® MicroSystem	Predicate device Exceed Microneedling Device (K180778)	Significant differences
	<ul style="list-style-type: none"> As a treatment to improve the appearance of facial acne scars in Fitzpatrick skin types I, II, and III in patients aged 22 years and older. As a treatment to improve the appearance of Periorbital wrinkles in Fitzpatrick skin types I, II, III, IV, V, and VI in adults aged 34 years and older. 		
Intended location of use	Face, Abdomen	Face (glabellar frown lines, periorbital lines and cheek folds)	Different. SkinStylus is indicated for periorbital wrinkles
Mode of action	Microneedling (using one or more needles to mechanically puncture and injure skin tissue for aesthetic use)	Microneedling (using one or more needles to mechanically puncture and injure skin tissue for aesthetic use)	Same
Needle geometry	36 solid needles (6 × 6 square)	6 needles in a squared arrangement	Different. Clinical and non-clinical performance testing demonstrates safety and effectiveness of the subject device for the proposed indication.
Needle length	2.5 mm	2.5 mm	Same
Needle protrusion setting	0.0 to 2.5 mm with marked 0.1 mm increments	0 to 1.9 mm	Same

Description	Subject device SkinStylus SteriLock® MicroSystem	Predicate device Exceed Microneedling Device (K180778)	Significant differences
Maximum needle penetration in clinical application	2.5 mm	1.5 mm	Different. Clinical and non-clinical performance testing demonstrates safety and effectiveness of the subject device for the proposed indication.
Accuracy of needle penetration depth	± 0.25 mm	Not stated in K180778 summary	Information not available. Clinical and non-clinical performance testing demonstrates safety and effectiveness of the subject device for the proposed indication.
Motor speed	6200 to 8840 RPM	100 to 150 Hz (±10%) 6000 to 9000 RPM	Similar – the motor speed range of the SkinStylus is within the range of the Exceed device.
Treatment protocol	Abdominal scarring: 3 treatments, at least 2 weeks between treatments Facial Acne: 4 treatments, at least 30 days between treatments	4 treatments spaced 4 weeks apart	Identical with respect to facial wrinkle indication.

Description	Subject device SkinStylus SteriLock® MicroSystem	Predicate device Exceed Microneedling Device (K180778)	Significant differences
	Periorbital Wrinkles: 4 treatments, at least 30 days between treatments		
Power source(s)	5 V DC/1 amp rechargeable lithium-ion battery, or AC adapter 5VC +/-, 1 A minimum	15 V DC	Different. Non-clinical performance testing demonstrates safety and effectiveness of the subject device for the proposed indication.

Substantial Equivalency and Comparison of Technological Similarities and Differences

Similarities between subject device and predicate

The Exceed Microneedling Device (K180778) is a microneedling system cleared for the same intended use and similar indication as proposed for the subject device. The key technological similarities between the SkinStylus SteriLock® MicroSystem and the Exceed Microneedling Device include:

- Both devices are microneedling systems containing >1 needle that uses a powered reciprocating motion to mechanically puncture or injure the skin for aesthetic use.
- Both devices are generally indicated for the treatment of facial wrinkles.
- Both devices use a sterile, single-use disposable needle cartridge with stainless steel microneedles.
- Both devices are intended for prescription use only and have identical treatment protocols.
- The subject device's motor speed range is within the operating range of the predicate.

Differences between subject device and predicate

The following differences are noted between the subject device and the Exceed system (K180778):

- Use of the Exceed system is indicated for facial wrinkles in the glabellar frown lines, periorbital lines and cheek folds area. The subject device is indicated for the periorbital region. Clinical performance testing supports the use of the subject device as described.
- The intended patient demographics of the subject device (age 34 years and older, Fitzpatrick skin type I-VI) differ from the patient demographics of the predicate device (age 22 years and older, Fitzpatrick skin type I, II, or III). Clinical performance testing included with this submission supports the targeted patient population of the subject device.

The subject device's needle cartridge uses 36 microneedles arranged in a 6 × 6 square, while the Exceed predicate device cartridge contains 6 microneedles arranged in a square. Additionally, the subject device has a greater maximum depth setting (2.5 mm vs 1.9 mm) and maximum permissible depth for the indication (2.5 mm vs 1.9 mm). Clinical performance testing demonstrates that the subject device needle cartridge and depth settings are safe and effective for the indicated use, and the safety of the device is further supported by postmarket data referenced via the MAUDE database.

The technological characteristics of the proposed device have been addressed by the sponsor through application of relevant safety standards (general controls and mitigation measures), special controls, and both clinical and non-clinical performance testing.

General controls and mitigation measures

The SkinStylus SteriLock® MicroSystem is subject to the general controls of the FD&C Act and special controls under 21 CFR 878.4430: To demonstrate safety and effectiveness and support substantial equivalence the device has undergone several non-clinical performance tests in line with recognized standards in terms of biocompatibility, electrical safety, software and general requirements.

Biocompatibility

The critical component of the SSSM device in terms of patient contact and biocompatibility is the SteriLock® cartridge.

The following testing data is provided to demonstrate the biocompatibility of the needles:

- ISO 10993-5:2009 tests for in vitro cytotoxicity
- ISO 10993-10:2010 tests for irritation
- ISO 10993-10:2010 tests for skin sensitization
- ISO 10993-11:2017 tests for systemic toxicity and pyrogens
- Chemical composition/metallographic analysis

The body of the cartridge is composed of polycarbonate. While the polycarbonate does not penetrate the skin surface, it may contact the surface of the skin during treatment. The following biocompatibility test data was provided to demonstrate biocompatibility endpoints for the polycarbonate:

- ISO 10993-5:2009 tests for in vitro cytotoxicity
- ISO 10993-10:2010 tests for irritation
- ISO 10993-10:2010 tests for skin sensitization
- ISO 10993-11:2017 tests for systemic toxicity and pyrogens

Sterility and shelf-life testing

The single-use SteriLock® needle cartridge is the only component of the system that is provided sterile and has been validated according to:

- ISO 11737-1:2018 Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products
- ISO 11737-2:2009 Sterilization of health care products – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

The single-use cartridge packaging has been validated to maintain sterility over the product's shelf-life according to:

- ASTM F88/F88M-15 Seal Strength of Flexible Barrier Materials
- ASTM F1929-15 Dye Penetration Test
- ASTM F1608 Microbial Ranking Test

EMC and electrical performance

The SSM has been tested to applicable industry standards for electromagnetic compatibility (EMC) and electrical safety and complies to the following:

- IEC 60601-1:2005 + CORR 1:2006 + CORR 2:2007 + A1:2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Battery testing

The Lithium-ion battery for the SSSM system has been tested and complies with the following standards:

- IEC 62133-2:2017, Secondary cells and batteries containing alkaline or other non-acid electrolytes. Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
- UN38.3 Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria (ST/SG/AC.10.11/Rev.6) Sixth revised edition.

Software

The SkinStylus SteriLock® MicroSystem does not incorporate **any** software in the device design.

Non-Clinical Performance

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

1. The technical specifications and needle characteristics have been identified, including needle length, geometry and maximum penetration depth.
 - a. Accuracy of the needle penetration depth and puncture rate
 - b. Safety features to protect against cross-contamination, including fluid ingress protection
 - c. Maximum safe needle penetration depth.
2. Validation was performed for reusable components of the device.

3. 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.
4. Maximum Shelf life.
5. Patient labeling included:
 - a. Information on how the device operates and the typical course of treatment.
 - b. The probable risks and benefits associated with use of the device; and
 - c. Post-operative care instructions.
6. Usability/Human factors. The subject device has been previously cleared under K200444 and K231073.

Clinical Performance

A clinical study was conducted to support the safety and effectiveness of the SkinStylus SteriLock® MicroSystem for the treatment of facial wrinkles.

The single-arm study was conducted at two centers and included treatments on day 0 (baseline), day 30, day 60, and day 90, with follow-up visits on day 120 and day 150. During each visit, standardized photography was taken, study investigators graded subjects' wrinkles, and subjects provided a self-evaluation of their facial wrinkles and associated psychological well-being. If the visit included a microneedling treatment, the treatment was performed after photography and other assessments. After treatment, subjects assessed side effects and received a diary to record their side effects over the following week. During day 90, day 120, and day 150 visits, investigators and subjects both provided additional assessments on the overall effectiveness of the treatment. Subjects reported any adverse events to the study site throughout the study period.

Each of the four treatments was performed by a trained and appropriately qualified operator. Facial skin was cleansed using Cetaphil® wipes before BLT numbing cream (Benzocaine 20%, Lidocaine 4%, Tetracaine 2%) was applied for 30 minutes. After the numbing cream was removed, a gliding agent (Supragel) was applied to the face before starting the microneedling procedure. All treatments were performed using a 36-pin (all @2.5 mm) cartridge. Each subject was treated on the forehead, cheek and nasolabial folds, periorbital area, glabella and jawline, and upper lip, corner of mouth and chin. Treatment of each area started at a depth of 0.5 mm and the depth was increased in increments of 0.1 mm until the clinical endpoint of pinpoint bleeding was observed. The modal depth setting used was Glabella -

1mm, Periorbital - 1.5mm, Cheek/ Nasolabial - 2mm, Forehead - 0.8mm, Perioral - 1.5mm and Chin - 1.5mm. After each treatment, the subject’s facial skin was cleansed with sterile saline and sterile gauze, then moisturizer and sunblock were applied.

A total of 51 subjects enrolled in the study. The following tables describe the demographics of the study group.

Age		Sex		Fitzpatrick skin type					
Mean	Range	Male	Female	I	II	III	IV	V	VI
54.7	34-72	2	49	3	13	18	9	4	4

Race		
Asian	2	4%
Black or African American	5	10%
Native Hawaiian or Other Pacific Islander	1	2%
White/Caucasian	39	76%
Mixed race	4	8%
Ethnicity		
Hispanic or Latino	13	25%
Not Hispanic or Latino	38	75%

The primary endpoint of the study was a mean improvement over baseline of one grade on the Lemperle scale for wrinkle assessment of the periorbital region, cheek folds, and glabellar lines at 120 days and 150 days after the first treatment. The Lemperle Wrinkle Grading Scale is a grading system used to assess the severity of facial wrinkles. The scale divides the face into distinct regions and provides a photonumeric scale to assess each individual area. Each area can be graded from 0 to 5, where 0 = no wrinkles and 5= Very deep wrinkles. Patient treatment satisfaction and psychological function measured on the FACE-Q scale at day 0 and day 150. Adverse events were recorded throughout the study period. In addition to the major endpoints Global Aesthetic Improvement Scale (GAIS) and Subject Global Aesthetic Improvement Scale (SGAIS) were used to assess overall improvement of facial appearance as judged by the clinical assessors and subjects respectively.

Standardized photography was taken at each study visit using VISIA systems. The images were randomized and three independent, blinded physicians graded the appearance of wrinkles on the VISIA images using the Lemperle scale.

Clinical Results

Reduction in Wrinkles Assessment (Primary Endpoint)

The average baseline grading for periorbital lines was 3.14 (range 1-4) at study site #1, and 2.06 (range 1-3) at study site #2. By day 120 (30 days after completing the fourth treatment),

the average grading for periorbital lines was 1.8 (range 0-3) at study site #1 and 1.8 (range 1-3) at study site #2, an improvement of 1.3 and 0.2 from baseline, respectively. By day 150 (60 days after completing the fourth treatment), the average grading for periorbital lines was 1.69 (range 0-3) at study site #1 and 1.67 (range 0-3) at study site #2, an improvement of 1.5 and 0.2 from baseline, respectively.

The primary endpoint was achieved for periorbital lines at site #1 (ASIRC), and the primary endpoint was not achieved for periorbital wrinkles at site #2 (WDRC).

Reduction in Wrinkle Assessment: Blinded evaluation of photos by independent physicians

Three independent physicians retrospectively graded subjects' wrinkles at baseline and day 150 using the Lemperle scale using VISIA images that were randomized and blinded.

The periorbital region showed the most consistent improvement, with 40 subjects (80%) rated as improved at Day 150 as agreed upon by at least 2 out of 3 independent photograph reviewers (study site #1: 27 (77%) subjects improved, 95% confidence interval [60%, 90%]; study site #2: 13 (87%) subjects improved, 95% confidence interval [60%, 98%]).

Adverse Event Results

No adverse incidents that were related to the study treatment were reported during the study.

Side Effects

Subjects' self-evaluations of side effects have been pooled for both sites.

Subjects' self-evaluations indicated that the pain was most severe (mean grading of 3.0, representing "moderate" pain) immediately following the treatment. Subjects' pain reduced quickly following treatment, to a mean grading of 1.1 by day 2 (the evening of the day after treatment) and completely resolving by day 6.

Subjects' self-evaluations indicated only mild discomfort, with the peak grading of 1.4 (mild discomfort) occurring the evening following the treatment. Discomfort resolved fully by day 8.

Subjects were asked to grade peeling and flaking beginning on day 3 (approximately 48-60 hours after treatment). Peak grading of peeling/flaking occurred on day 4 (mean grading of 1.9, mild peeling/flaking), and by day 8 the mean grading was 0.5 (very mild).

Subjects' self-evaluations indicated that erythema was most severe immediately following treatment, with all subjects reporting some degree of erythema: 74.5% moderate to severe and 25.5% minor to mild. Erythema improved significantly by day 2, with only 18.5% of subjects reporting moderate to severe erythema, 76% reporting minor to mild erythema, and 5.5% reporting no erythema. By day 8, no subjects reported their erythema was moderate to

severe, only 11.5% reported minor to mild erythema, and 88.5% reported that their erythema had resolved completely.

Additional Results

Physician grading of treatment response (GAIS)

Mean grading of subjects' overall treatment response by the investigator on day 90 was 2.3 (good improvement) at study site #1 and 1.4 (fair improvement) at study site #2. By day 150 (60 days after the last treatment), mean grading was 2.9 at study site #1 (very good improvement) and 2.5 at study site #2 (good to very good improvement), an increase of 0.6 and 1.1, respectively.

On day 90, investigators graded 48 of 50 subjects as showing some degree of improvement, and only two subjects as showing poor/no improvement. The modal grading at day 90 was 3 (very good) at study site #1 and 1 (fair) at study site #2. By day 150, investigators graded all subjects as showing some improvement, with 32 of 50 subjects showing very good or excellent improvement. The modal grading at day 150 was 3 (very good) study site #1 and 2 (good) at study site #2.

Subject self-evaluation of treatment response (SGAIS)

Mean self-evaluation by subjects of overall treatment response on day 90 was 2.3 (good improvement) at study site #1 and 1.7 at study site #2. By day 150 (60 days after the last treatment), subjects' mean grading was 2.7 at study site #1 and 2.3 at study site #2, an increase of 0.4 and 0.6 respectively.

On day 90, 49 of 50 subjects reported some degree of improvement, and only one subject graded their appearance as having poor/no improvement. The modal grading at day 90 was 3 at study site #1 and 1 at study site #2. By day 150, 48 of 50 subjects reported some degree of improvement, with 24 reporting very good or excellent improvement, 24 reporting fair or good improvement, and two reporting poor improvement. The modal SGAIS grading at day 150 was 2 at both study sites.

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.

Esthetic Medical has demonstrated that the SkinStylus SteriLock® MicroSystem has the same generic classification (generic description) and basic technologies as the predicate

devices. The SkinStylus and both predicates are all prescription micro needling systems for use in a physician/aesthetician clinic setting that use multiple needles to mechanically puncture or injure the skin for aesthetic use. The specific indication for the treatment of facial wrinkles in the periorbital region is shared between the subject device and the Exceed Microneedling Device predicate, and Esthetic Medical has undertaken clinical testing that demonstrates the SkinStylus SteriLock® MicroSystem's effectiveness in treating facial wrinkles in the periorbital region.

Esthetic Medical has conducted both 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 SkinStylus SteriLock® MicroSystem raises no new questions relating to safety and therefore has demonstrated that the SkinStylus SteriLock® MicroSystem is substantially equivalent to the Exceed Microneedling Device (K180778).

February 19th 2025