July 28, 2023

Esthetic Medical Inc.
% Marc Sanchez
Regulatory Attorney
Contract In-House Counsel and Consultants,
LLC (d/b/a FDA Atty)
1717 Pennsylvania Ave NW Suite 1025
Washington, District of Columbia 20006

Re: K231073
Trade/Device Name: SkinStylus SteriLock® MicroSystem, Model Number MP1209SL
Regulation Number: 21 CFR 878.4430
Regulation Name: Microneedling Device For Aesthetic Use
Regulatory Class: Class II
Product Code: QAI
Dated: May 12, 2023
Received: May 12, 2023

Dear Marc Sanchez:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.07.28 13:54:57 -04'00'

Mark Trumbore, Ph.D.
Assistant 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)*

Device Name
SkinStylus SteriLock® MicroSystem

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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

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

5. 510(K) Summary

The following information is provided as required by 21 CFR 807.92 for the SkinStylus SteriLock® MicroSystem 510(k) premarket notification.

Sponsor: Esthetic Medical Inc.
Attention: Lawrence Groop
7950 E. Acoma Drive Suite 208
Scottsdale, AZ 85260

Establishment Registration: 3011338460

Manufacturer: GUANGZHOU CARAIN BEAUTY EQUIPMENT
103 & 601, No. 3 of Xin Liu Mu Road,
Zhong Cun Street
Guangzhou Guangdong, CHINA 511495
Establishment Registration: 3011568699

Contact: Marc C. Sanchez, Esq.
Contract In-House Counsel and Consultants, LLC (d/b/a FDA Atty)
1717 Pennsylvania Ave NW Suite 1025 Washington D.C. 20006
Ph: 202.765.4491
E-mail: msanchez@fdaatty.com

Date of Submission: July 28, 2023

Proprietary Name: SkinStylus SteriLock® MicroSystem

Common Name: Powered Microneedle Device

Regulation Number: 21 CFR 882.4810

Regulatory Class: Class II

Product Code: QAI

Predicate Device(s): Collagen P.I.N. (Percutaneous Induction Microneedling) System (K222199).

Device Description:

The SkinStylus SteriLock® MicroSystem is a handheld device that creates channels as well as microinjuries into the skin, by virtue of a 1A DC motor that rapidly reciprocates an array of 32 gauge microneedles that are no longer than 2.5mm. The device consists of a power source, a motor body with depth adjustment, a removable nosecone interface, and a disposable, single use cartridge containing an array of microneedles.

The power source consists of two separate systems. One option is a rechargeable lithium-ion battery that delivers no more than 5 volts DC and 1 amp of current to power the motor. The other option consists of an AC wall adaptor that converts 110v AC into 5v DC. A power cord connects the wall adaptor to the device via a USB connector and a standard 1/8" headphone plug on the device side.

The motor body is comprised of anodized aluminum with a dial mechanism that controls the depth of penetration of the microneedles from 0.0 mm to a maximum of 2.5mm.

The removable nosecone interface provides the SkinStylus® the unique ability to have an interface between the motor and the cartridge to ensure there is a secondary control preventing any fluid from entering the motor body. The removable nosecone is autoclave sterilized after every use.

The SkinStylus® disposable cartridge is designed in a 36-needle array with all needles at 2.5mm. The needle array is housed in a specially designed and patented cartridge housing that prevents liquids from entering the motor body via the inside lumen of the cartridge.

The SkinStylus SteriLock® microneedles are composed of 304 18/8 surgical steel tested and certified as biocompatible under GLP testing conditions that conform to ISO 10993-5, 10993-10, and 10993-11. A metallurgical analysis under GLP testing conditions that conform to ASTM E1019-11(Method A)(C/S Analyzer) was also completed and is attached.

Each lot of cartridges are individually packaged and then gamma ray sterilized by TUV Sud accredited facility under procedure code P1501314 with a minimum dose of 25kGy under report #GM2015012518. Certifications on file with sponsor and available for review.

Intended Use:

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 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.

Summary of Clinical Test Reports

A new clinical trial was not conducted to support the additional indications for use and overall safety of the device.

Non-Clinical Test Reports

The following tests were performed on the SkinStylus SteriLock® MicroSystem device and the test results show that the subject device is substantially equivalent to the predicate Device.

Table 1
Summary of Non-Clinical Performance Testing

Test Completed	Standard
Biocompatibility[A]	
	Cytotoxity - ISO 10993-5:2009
	Sensitization –ISO 10993-10:2010
	Irritation - lntracutaneous Injection Test GLP - ISO 10993-10:2010
	Systemic Toxicity – Systemic Injection GLP - ISO 10993-11:2017
	Pyrogenicity ISO 10993
	Metallurgical Analysis – GLP - ASTM E1019-11(Method A)(C/S Analyzer)
Sterilization Validation[B]	Sterilization of Health Care Products – Moist heat ISO 17665-1:2006 Sterilization of Medical Devices ISO 11737-1: 2006 Sterilization of Medical Devices ISO 11737-2: 2009 Sterility and Bacteriostasis/Fungistasis Tests ISO 11737-2: 2009 and USP 71
Reprocessing Validation[B]	ISO 11737-1: 2018 (AAMI TIR-30; 2011; AAMI TIR-12:2004)
Fluid Ingress Validation[B]	SkinStylus Sterilock Microsystem Leak Testing Report from MicroChem Laboratories
Shelf-life Testing[B]	Standard Test Method for Seal Strength of Flexible Barrier Materials ASTM F88/F88M-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration ASTM F1929-15

	Standard Test Method for Microbial Ranking of Porous Packaging Materials ASTM F1608-16
Electrical Safety and Electromagnetic Compatibility[C]	IEC 60601-1-2 and 60601-1
Depth Penetration Validation[D]	Internal Method - Depth Penetration Report
Needle Reciprocal Rate Validation	Internal Method - Needle Reciprocal Rate Report
Clinician Usability Study	Internal Method – Usability Report

[A] Mitigation measure for adverse tissue reaction.

[B] Mitigation measure for cross-contamination and infection.

[C] Mitigation measure for electrical shock or electromagnetic interference with other devices.

[D] Mitigation measure for Damage to underlying tissue including nerves and blood vessels, scarring, and hyper/hypopigmentation due to exceeding safe penetration depth or mechanical failure.**

**NOTE: *The proposed device contains NO software*

Summary of Substantial Equivalence

The SkinStylus SteriLock® MicroSystem and the predicate are for similar uses and rely on the same mode of action. Both devices include disposable needle cartridges with design features to mitigate the likelihood of cross-contamination between patients and to prevent needle depth greater than 2.5mm. Both devices also include a redundant safety feature to ensure no fluid enters the motor or housing.

Table 2
Technological Characteristics

Device Name/Model	SkinStylus SteriLock® MicroSystem Subject Device	Collagen P.I.N. (Percutaneous Induction Microneedling) System Predicate Device	SkinStylus SteriLock® MicroSystem Reference Device	Comments
510(k) Number	K231073	K222199	K200044	N/A
Indication for Use	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.	Intended to be used as a treatment to improve the appearance of facial acne scars in Fitzpatrick skin types I-III in patients aged 22 years and older	Intended to be used as a treatment to improve the appearance of hypertrophic abdominal scarring	Subject device same as predicate device
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)	Microneedling (using one or more needles to mechanically puncture and injure skin tissue for aesthetic use)	Same
Power Source 1	5 Volt DC/1 amp rechargeable lithium-ion battery	5 Volt DC/1 amp rechargeable lithium-ion battery	5 Volt DC/1 amp rechargeable lithium-ion battery	Same
Power Source 2	AC Adapter 5VC +/-, 1A minimum	AC Adapter 5VC +/-, 1A minimum	AC Adapter 5VC +/-, 1A minimum	Same
Range of Needle Length	0.0-2.5mm	0.0mm-3.0mm	0.0-2.5mm	- Similar to predicate device -Needle penetration of subject device is .5mm less than predicate device which has been cleared to 3.0mm
Maximum Penetration	2.5mm	3.0mm	2.5mm	- Similar to predicate device -Needle penetration of subject device is .5mm less than predicate device which has been cleared to 3.0mm

Esthetic Medical Inc.

Needle Geometry	36 solid needles	36 solid needles	36 solid needles	Same
Speed	6200- 8840 RPM	7000 RPM-9000 RPM	6200- 8840 RPM	Negligible difference in RPM Does not impact the safety or efficacy of the subject device
Cross Contamination Safety Feature	Cartridge design and intermediate disinfected handpiece and nosecone with optional reprocessed (autoclave sterilized) nosecone;	Cartridge design and intermediate disinfected handpiece and nosecone with optional reprocessed (autoclave sterilized) nosecone;	Cartridge design and intermediate disinfected handpiece and nosecone with optional reprocessed (autoclave sterilized) nosecone;	Same
Sterility and Cleaning	Disposable cartridge Gamma Ray Sterilized prior to packaging	Disposable cartridge Ethylene Oxide Sterilized prior to packaging	Disposable cartridge Gamma Ray Sterilized prior to packaging	Both devices use approved methods for cartridge sterilization. Does not impact the safety or efficacy of the subject device

Conclusion:

Therefore, taking into consideration Table 2 for Substantial Equivalence, an analysis of safety, indications, intended uses, performance, and technological properties, the SkinStylus SteriLock® MicroSystem raises no new issues of safety or effectiveness and has been found to be substantially equivalent to the predicate device. Further, the predicate device has been cleared for 3.0mm needle penetration, whereas the subject device (and already cleared reference device) has a maximum needle penetration of only 2.5mm.