October 9, 2024

Su-Ko Technologies LLC
℅ Marc Sanchez, Esq.
Regulatory Counsel
Contract In-House Counsel and Consultants,
LLC d/b/a FDA Atty
1717 Pennsylvania Ave NW Suite 1025
Washington, District of Columbia 20006

Re: K241355
Trade/Device Name: SER Pen Carain MicroSystem (MP1209SP)
Regulation Number: 21 CFR 878.4430
Regulation Name: Microneedling Device For Aesthetic Use
Regulatory Class: Class II
Product Code: QAI
Dated: September 11, 2024
Received: September 11, 2024

Dear Marc Sanchez, Esq.:

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,

Wilmarie Flores -S

Wilmarie Flores, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241355

Device Name
SER Pen Carain MicroSystem (MP1209SP)

Indications for Use *(Describe)*
The SER Pen Carain MicroSystem is intended for use as a treatment to improve the appearance of facial acne scars in adults with Fitzpatrick Skin Types I - III, aged 22 years and older and as a treatment to improve the appearance of surgical or traumatic hypertrophic scars on the abdomen 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.

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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."

510(K) Summary

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

Sponsor: Su-Ko Technologies, LLC
Attention: Yuan Yuan Korrodi
700 Smith Street, #61070
Houston, TX 77002

Manufacturer: GUANGZHOU CARAIN BEAUTY EQUIPMENT
501, 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: October 8, 2024

Proprietary Name: SER Pen Carain MicroSystem (MP1209SP)

Common Name: Powered Microneedle Device

Regulation Number: 21 CFR 882.4810

Regulatory Class: Class II

Product Code: QAI

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

Secondary Predicate Device: SkinStylus SteriLock® MicroSystem (K200044).

Device Description:

The SER Pen Carain MicroSystem (MP1209SP) is a handheld device that creates channels as well as microinjuries into the skin, by virtue of a DC motor drive system that rapidly reciprocates an

array of 12 needles and 36 needles that are no longer than 2.5mm. The device consists of a power source, a motor body with depth adjustment, and a disposable, single use cartridge containing an array of needles.

The power source consists of a rechargeable lithium-ion battery that delivers no more than 5 volts DC and 1 amp of current to power the motor. 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 SER Pen Carain MicroSystem's disposable cartridge is designed in two configurations, a 12-needle array and a 36-needle array. The needle array is housed in a specially designed cartridge housing with a silicon spring that prevents liquids from entering the motor body via the inside lumen of the cartridge.

The SER Pen Carain MicroSystem biolock sleeve is a one end elastic opening PE bag to protect the whole system from cross contamination from the outside during the operation procedure.

The SER Pen Carain MicroSystem 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. Certifications on file with the Sponsor and available for review.

Indications for Use:

The SER Pen Carain MicroSystem is intended to be used as a treatment to improve the appearance of facial acne scars in adults with Fitzpatrick Skin Types I - III, and to improve the appearance of surgical or traumatic hypertrophic scars on the abdomen in adults aged 22 years and older.

Summary of Non-Clinical Test Reports

The Sponsor intends to rely on the same performance data submitted in Collagen P.I.N. (K222199) and SkinStylus (K200044 and K231073) devices and *not* include any clinical data. Specifically, the Sponsor intends to rely on the following performance data reports.

Test Completed	Standard
Biocompatibility	
	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	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	ISO 11737-1: 2018 (AAMI TIR-30; 2011; AAMI TIR-12:2004)
Fluid Ingress Validation	

Shelf-life Testing	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

Summary of Substantial Equivalence

The SER Pen Carain 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	SER Pen Carain MicroSystem (MP1209SP)	Collagen P.I.N. (Percutaneous Induction Microneedling) System	SkinStylus SteriLock® MicroSystem
510(k) Number	t/b/d	K222199	K200044
Indication for Use	The SER Pen Carain MicroSystem is intended to be used as a treatment to improve the appearance of facial acne scars in adults with Fitzpatrick Skin Types I - III, and to improve the appearance of surgical or traumatic hypertrophic scars on the abdomen in adults aged 22 years and older.	for use as a treatment to improve the appearance of facial acne scars in adults with Fitzpatrick Skin Types I - III, aged 22 years and older.	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.
Mode of Action	Identical	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)

Su-Ko Technologies,

Power Source	Same 5Volt 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
Length/Width/shape/ weight of both handpiece and cartridge	Identical	Identical	Identical
Range of Needle Length	0.0-2.5mm	0.0mm-3.0mm	0.0-2.5mm
Maximum Penetration	2.5mm	3.0mm	2.5mm
Needle Geometry	Identical, 12 or 36 solid needles	36 solid needles	12 solid needle
Speed	Identical , 6200RPM-900 0 RPM	7000RPM-9000 RPM	6200RPM-9000 RPM
Sterility and Cleaning	Same. Disposable cartridge Gamma Ray Sterilized prior to packaging	Disposable cartridge Ethylene Oxide	Disposable cartridge Gamma Ray Sterilized prior to packaging
Cross Contamination Feature	Identical:Cartridge design with a sealing spring inside the cartridge housing, and a biolock sleeve to cover from the cartridge outshell and the whole handpiece to stop cross contamination.	**Same**	Cartridge design and intermediate disinfected handpiece and nosecone with optional reprocessed (autoclave sterilized) nosecone;

Conclusion:

Therefore, taking into consideration Table 1 for Substantial Equivalence, an analysis of safety, indications, intended uses, performance, and technological properties, the SER Pen Carain MicroSystem raises no new issues of safety or effectiveness and has been found to be substantially equivalent to the predicate device.