



October 29, 2025

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

Re: K253153

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 24, 2025

Received: September 26, 2025

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 (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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Wilmarie** Digitally signed  
**Flores -S** by Wilmarie  
Flores -S

For Jodie Giordano, 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

## Indications for Use

510(k) Number (if known)

K253153

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.

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## **Special 510(k) Summary K253153**

SER Pen Carain MicroSystem (Model MP1209SP)

### **1. Submitter Information**

Sponsor: Su-Ko Technologies, LLC  
7801 N Lamar Blvd, Suite F34  
Austin, TX 78752

Manufacturer: Guangzhou Carain Beauty Equipment Co., Ltd  
Room 901-1, Blvd. No. 8 of CIMC High-Tech Manufacturing Center  
Chencun Town, Shunde District, Foshan City, Guangdong, China 528313

Contact Person: Marc C. Sanchez, Esq.  
Contract In-House Counsel and Consultants, LLC (d/b/a FDA Atty)  
1717 Pennsylvania Ave NW, Suite 1025  
Washington, DC 20006  
Tel: 202-765-4491  
Email: msanchez@fdaatty.com

### **2. Device Identification**

Proprietary Name: SER Pen Carain MicroSystem (Model MP1209SP)  
Common Name: Powered Microneedle Device  
Regulation Number: 21 CFR 882.4810  
Regulatory Class: Class II  
Product Code: QAI  
Submission Type: Special 510(k) (Design Modification)  
510(k): K253153  
Date: October 28, 2025

### **3. Predicate Devices**

Primary Predicate: SER Pen Carain MicroSystem (K241355)  
The subject device is substantially equivalent to the cleared SER Pen Carain MicroSystem (K241355) with modifications as described.

### **4. Device Description**

The SER Pen Carain MicroSystem is a handheld powered microneedling device consisting of a rechargeable motorized handpiece and disposable, single-use needle cartridges (12-pin and 36-pin). Microneedles are made of surgical-grade stainless steel (304) and are gamma sterilized.

Design modifications include:

- Addition of a powered 7-speed control head (6,200–9,000 RPM) with direct corded power option.
- Modified disposable cartridge (Model T2.0), shortened by 7 mm, with protective cap and compensatory spring.

No changes were made to the intended use, indications for use, or fundamental technology.

## **5. 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.

There are no changes to the indications for use.

## **6. Summary of Technological Characteristics**

The modified device has the same fundamental scientific technology as the predicate device:

- Mode of Action: Microneedling using reciprocating stainless steel needles.
- Energy Source: Rechargeable DC motor (5V, 1A).
- Maximum Penetration Depth: 2.5 mm.
- Needle Arrays: 12-pin or 36-pin.

The design modifications (7-speed control head, cartridge T2.0) do not alter these characteristics.

## **7. Performance Data**

Verification and validation testing was conducted to confirm safety and performance:

- Electrical Safety & EMC: IEC 60601-1, 60601-1-2 (PASS).
- Mechanical Durability: Control head and cartridge T2.0 (PASS).
- Depth Penetration: Accuracy within  $\pm 0.25$  mm, 98.9% passing (PASS).
- Reciprocation Testing: RPM within  $\pm 5\%$  (air) and  $\pm 10\%$  (substrate) (PASS).
- Biocompatibility: Needles unchanged; ISO 10993 compliance (PASS).
- Sterilization: Gamma irradiation validated (PASS).

Results confirm the device modifications do not raise new safety and effectiveness questions.

## **8. Conclusion**

The SER Pen Carain MicroSystem with design modifications (powered 7-speed control head and cartridge T2.0) is substantially equivalent to the predicate device (K241355). The modifications do not raise new questions of safety or effectiveness.