



May 13, 2026

Woorhi Mechatronics Co., Ltd.  
Jungsu Lee  
Official Correspondent  
58, Sanbon-ro, 48beon-gil  
Gunpo-si, Gyeonggi-do 15846  
Republic Of Korea

Re: K252591

Trade/Device Name: Automatic Micro Needle System (CODE-X)

Regulation Number: 21 CFR 878.4430

Regulation Name: Microneedling device for aesthetic use

Regulatory Class: Class II

Product Code: QAI

Dated: April 12, 2026

Received: April 13, 2026

Dear Jungsu Lee:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Digitally signed  
Wilmarie Flores -S by Wilmarie  
Flores -S

For Jodie Giordano, Ph.D.  
Assistant Director  
DHT4B: Division of Infection Control and Plastic 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)  
K252591

Device Name  
Automatic Micro Needle System (CODE-X)

### Indications for Use (Describe)

The Automatic Micro Needle System (CODE-X) 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.

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.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"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

## K252591

### Submitter

Woorhi Mechatronics Co., Ltd.

Woo Yong Woon

58, Sanbon-ro 48beon-gil, Gunpo-si, Gyeonggi-do, Republic of Korea

Email: cns@cnsbest.co.kr

Tel.: +82-70-4736-1118

### Device Information

- Trade Name: Automatic Micro Needle System (CODE-X)
- Common Name: Microneedling Device
- Classification Name: Microneedling Device For Aesthetic Use
- Product Code: QAI
- Panel: General and Plastic Surgery
- Regulation Number: 21 CFR 878.4430
- Device Class: Class II (Special Controls)
- Date Prepared: 04/09/2026

### Predicate Devices:

#### Primary Predicate

- K230420, Dr.pen Microneedling System by GC AMERICA INC. (Guangzhou Ekai Electronic Technology Co., Ltd.)

### Indication for Use:

The Automatic Micro Needle System 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.

### Device Description:

The CODE-X Automatic Micro Needle System is a motorized, AC-powered microneedling device designed to mechanically create microscopic channels in the epidermal and upper dermal layers of the skin for aesthetic use. The device delivers controlled microneedle penetration through a reciprocating needle cartridge driven by the motorized handpiece with embedded microprocessor control.

The system consists of the following components:

- Motorized handpiece (reusable) with adjustable needle depth control
- Sterile, single-use disposable microneedle cartridges (12-pin and 14-pin, EO sterilized)
- AC power adapter

The technical specifications of the device are as follows:

<b>Parameter</b>	<b>Specification</b>
<b>Power Source</b>	AC Powered
<b>Control Mechanism</b>	Microprocessor (Embedded software)
<b>Needle Configuration</b>	12-pin and 14-pin cartridges
<b>Needle Gauge/Diameter</b>	33G (.02 mm)
<b>Needle Shape/Geometry</b>	Straight, cylindrical body with a conical tapered, sharp point
<b>Needle Spacing</b>	2 mm spacing / 3.96 <sup>2</sup> mm per needle
<b>Needle Arrangement</b>	Needles radially arranged
<b>Adjustable Penetration Depth</b>	0 mm to 2.0 mm in 0.20 mm increments
<b>Recommended Penetration Depth</b>	1.5 mm
<b>Maximum Penetration Depth</b>	2.0 mm
<b>Sterilization (Cartridge)</b>	Ethylene Oxide (EO), single-use
<b>Shelf Life</b>	3 years
<b>Biocompatibility</b>	According to ISO 10993-1
<b>Intended Use Environment</b>	Professional healthcare setting (Rx)

## Substantial Equivalence Comparison

Characteristic	Proposed Device	Predicate Device	Comparison
<b>Device Name</b>	Automatic Micro Needle System (CODE-X)	Dr.pen Microneedling System	-
<b>Manufacturer</b>	Woorhi Mechatronics Co., Ltd.	GC AMERICA INC.	-
<b>510(k) Number</b>	K252591	K230420	-
<b>Regulatory Classification</b>	Class II	Class II	-
<b>Classification Name</b>	Microneedling Device For Aesthetic Use	Microneedling Device For Aesthetic Use	-
<b>Product Code</b>	QAI	QAI	-
<b>Indications for Use</b>	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.	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.	Equivalence
<b>Intended Location of Use</b>	Skin (Face)	Skin (Face)	Equivalence
<b>Power Source</b>	AC Powered	AC Powered	Equivalence
<b>Control Mechanism</b>	Microprocessor (Embedded software)	Microprocessor (Embedded software)	Equivalence
<b>Microneedling Cartridge</b>	Sterile, Single use	Sterile, Single use	Equivalence
<b>No. of Needles</b>	12-pin, 14-pin	14-pin	<b>Difference</b>
<b>Needle Shape/Geometry</b>	Straight, cylindrical body with a conical tapered, sharp point	Straight, cylindrical body with a conical tapered, sharp point	Equivalence
<b>Needle Spacing</b>	2 mm spacing / 3.96 <sup>2</sup> mm per needle	2 mm spacing / 3.96 <sup>2</sup> mm per needle	Equivalence
<b>Penetration Depth (Recommended)</b>	1.5 mm	1.5 mm	Equivalence
<b>Max Needle Setting</b>	2.0 mm	2.0 mm	Equivalence
<b>Penetration Depth Selection</b>	0 mm to 2.0 mm in 0.20 mm increments	0 mm to 2.0 mm in 0.25 mm increments	<b>Difference</b>
<b>Needle Arrangement</b>	Needles radially arranged	Needles radially arranged	Equivalence
<b>Sterility</b>	Ethylene Oxide	Ethylene Oxide	Equivalence
<b>Shelf Life</b>	3 years	2 years	<b>Difference</b>
<b>Clinical Performance</b>	Not applicable	Not applicable	Equivalence
<b>Biocompatibility</b>	According to ISO 10993-1	According to ISO 10993-1	Equivalence

**# Substantial Equivalence:** The Automatic Micro Needle System (CODE-X) is substantially equivalent to the Dr.pen Microneedling System (K230420) predicate device. The devices are under the same product code (QAI), have the same intended use/indication for use, same needle shape and arrangement, same material, recommended penetration depth, and sterilization method. The only technological differences are the number of needle options (additional 12-pin), penetration depth selection increment (0.20 mm vs. 0.25 mm), and shelf life (3 years vs. 2 years). These differences are either verified with performance data or are judged to have no significant impact on achieving the intended use.

## **Non-Clinical Test Data**

Below tests were performed on the subject device to demonstrate compliance with 21 CFR 878.4430 special controls:

- Penetration Depth Accuracy Testing (0.5, 1.0, 2.0 mm settings; n=10 per setting; all within  $\pm 5\%$  tolerance)
- Maximum Safe Penetration Depth Verification (3 devices  $\times$  10 measurements = 30 total; all  $\leq 2.1$  mm; 95% CI [1.992, 2.008])
- Needle Structural Integrity Testing (1,000 penetration cycles; no fracture or deformation)
- Cartridge Attachment Security Testing (30 attach/detach cycles across 3 devices; no loosening)
- Electrical Safety Testing per IEC 60601-1
- EMC Testing per IEC 60601-1-2
- Biocompatibility Testing per ISO 10993-1
- EO Sterilization Validation per ISO 11135
- Packaging and Shelf Life Validation per ISO 11607 and ASTM D4169
- Reprocessing Validation for reusable handpiece
- Software Verification and Validation
- Human Factors Validation Testing

The results of the above tests demonstrate that the device performs as intended under anticipated conditions of use and meets the special controls requirements of 21 CFR 878.4430. Non-clinical performance data confirm that the device is substantially equivalent as the predicate device.

Clinical testing was not necessary to establish substantial equivalency of the device.

## **Conclusion**

The Automatic Micro Needle System (CODE-X) constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This device has the same intended use and fundamental scientific technology as its predicate device (Dr.pen Microneedling System, K230420). Therefore, the CODE-X Automatic Micro Needle System and its predicate are substantially equivalent.