February 6, 2026

Shenzhen GSD Technology Co., Ltd.
Gordon Wang
Director of US Operations
Building A, JUNSD Hi-Tech Park, Watch & Clock Base
Guangming District
Shenzhen
China

Re: K251836
Trade/Device Name: Dermatrix Duo
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 31, 2025
Received: January 6, 2026

Dear Gordon Wang:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.02.06 10:14:15 -05'00'

Colin Kejing Chen, Ph.D.
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251836

Please provide the device trade name(s).

Dermatrix Duo

Please provide your Indications for Use below.

The Dermatrix Duo is intended for use in dermatologic procedures for electrocoagulation and hemostasis.

The SFR applicator is indicated for:
• Relief of minor muscle aches and pain, relief of muscle spasm
• Temporary improvement of local blood circulation

Please select the types of uses (select one or both, as applicable).

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

510(K) Summary
Dermatrix Duo K251836

Applicant	Shenzhen GSD Technology Co., Ltd.
Address	Building A, JUNSD Hi-Tech Park, Watch & Clock Base Guangming District Shenzhen, China
Contact Person	Gordon Wang – Director of US Operations
Contact Information	gordonw@usagsdaesthetics.com (949)870-5576
Preparation Date	February 3, 2026
Device Trade Name	Dermatrix Duo
Classification Name	Electrosurgical Cutting and Coagulation Device and Accessories
Regulation Number	878.440, 882.5890
Product Code	GEI, PBX
Regulatory Class	II
Legally Marketed Predicate Devices	Virtue RF (K211562) Endymed Mini-Shaper Max Handpiece(K242996)

Device Description:

The Dermatrix Duo system includes the system main body, a footswitch and two handpieces, the Microneedle RF (MFR) and the Superficial RF (SFR). The MFR handpiece is a microneedling handpiece that has 2 different configurations of cartridges: a 16 needle and a 49 needle. The SFR handpiece has 1 configuration consisting of 64 non-invasive tips. The control panel is equipped with an LCD touch screen so that users may easily adjust parameters for optimal settings. The software provides device and clinical information to the users.

The MFR handpiece creates heat within the target dermal tissue via micro needles inserted into the tissue. The microneedle cartridges are sterilized using ethylene oxide.

Using the SFR handpiece, the Dermatrix Duo system creates heat within the target dermal tissue via a matrix of electrodes on the SFR tip. There is only one type of handpiece tip (8x8 RF electrodes) that is non-sterile.

RF energy is delivered to the target tissue using the handpiece, the tip of the handpiece being placed in light contact with the epidermis, and the handpiece being held at right angles to the target tissue. As the

RF energy passes through the skin, it generates an electrothermal reaction which is capable of achieving controlled coagulation of the target tissue.

Indications for use:

The Dermatrix Duo is intended for use in dermatologic procedures for electrocoagulation and hemostasis

The SFR applicator is indicated for:

- Relief of minor muscle aches and pain, relief of muscle spasm
- Temporary improvement of local blood circulation

Substantial Equivalence—Indications for use and Technical Comparison

Indications for use and Technical Comparison for the RF Microneedle

Spec	Dermatrix Duo(Subject Device)	Virtue RF (Predicate Device	Vybe RF (Reference Device)	Comparison
Indications	The Dermatrix Duo is intended for use in dermatologic procedures for electrocoagulation and hemostasis. The SFR applicator is indicated for: • Relief of minor muscle aches and pain, relief of muscle spasm • Temporary improvement of local blood circulation	The VYBE RF II is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis and the percutaneous treatment of facial wrinkles for use with Fitzpatrick Skin Type I to Skin Type V. The Microneedle Array Handpiece with 2 MHz functionality is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The Microneedle Array handpiece with 2MHz functionality is not intended to treat wrinkles.	The VYBE RF II is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis and the percutaneous treatment of facial wrinkles for use with Fitzpatrick Sky Type I to Skin Type V. The Microneedle Array Handpiece with 2 MHz functionality is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The Microneedle Array handpiece with 2MHz functionality is not intended to treat wrinkles.	Same for the 1MHz frequency. The subject device does not have 2MHz. The indication for use statement is different.
Product Code	GEI	GEI	GEI	
Operation	Radiofrequency Microneedling	Radiofrequency Microneedling	Radiofrequency Microneedling	Same
# of Needles	49 needles tip 16 needles tip	36 needle tip 1 needle tip	36 needle tip 1 needle tip	Different – Histology was conducted to

Spec	Dermatrix Duo(Subject Device)	Virtue RF (Predicate Device	Vybe RF (Reference Device)	Comparison
				show that there is no difference regardless of the needles configuration
Microneedle Cartridge exposed length	Up to 3.5mm	Up to 3.5mm	Up to 3.5mm	Same
Microneedle diameter	0.2mm	0.3mm	0.3mm	Different: The subject device has a slightly smaller diameter needle. The histology testing showed that the subject device is equivalent
Frequency	1mHz	2MHz, 1MHz	2MHz, 1MHz	Different. The Subject device does not have 2MHz frequency
Modality	Bipolar	Monopolar and Bipolar	Monopolar and Bipolar	Different – the Subject device is only BiPolar
Max Power	50W	35.9W@1mHz 25W@2mHz	59W@1mHz 25W@2mHz	Different from the predicate device but slightly lower than the reference device. Histology was conducted to show

Spec	Dermatrix Duo(Subject Device)	Virtue RF (Predicate Device	Vybe RF (Reference Device)	Comparison
				that the devices are similar regardless of the max power
RF Duration	10ms – 400ms	100ms-200ms with 100ms increments	100ms-200ms with 100ms increments	Different – histology was conducted to demonstrate equivalence

Indication and technical specification for the RF Noninvasive Electrodes

Specification	Dermatrix Duo(Subject Device)	**Predicate Device EndyMed MiniShaper Max**	**Comparison**
Indications	The Dermatrix Duo is intended for use in dermatologic procedures for electrocoagulation and hemostasis. The SFR applicator is indicated for; • Relief of minor muscle aches and pain, relief of muscle spasm • Temporary improvement of local blood circulation	The Mini-Shaper MAX Handpiece is Indicated for • Relief of minor muscle aches and pain, relief of muscle spasm • Temporary improvement of local blood circulation	Same
Mode of operation	Non-invasive bipolar radiofrequency	Non-invasive bipolar radiofrequency	Same
RF output frequency	1MHz	1MHz	Same
RF output max power	50W	Up to 70W	Different – The subject device is a lower max power, but the thermal testing

Specification	Dermatrix Duo(Subject Device)	**Predicate Device EndyMed MiniShaper Max**	**Comparison**
			showed that the device can achieve the intended use.
Pulse Duration	10-400 ms	Up to 30 seconds	Different – The subject device has a shorter pulse duration but the thermal testing showed that the device can achieve the intended use
Electrode area	441 mm^2	614.7mm^2	Different.

Performance Testing

Verification and validation activities were successfully completed and establish that the Dermatrix Duo performs as intended. Testing included the following:

- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION
- IEC 60601-1-2:2014 [Including AMD 1:2021]
- IEC TS 60601-4-2 Edition 1.0 2024-03
- IEC 60601-2-2:2017 + A1:2023; Medical Electrical Equipment –part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgical Equipment And High Frequency Surgical Accessories
- ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- IEC 62304:2006+A1:2015; Medical Device – Software Life Cycle Processes
- EN ISO 14971:2012; Medical Devices – Application Of Risk Management To Medical Devices

The biocompatibility evaluation for the Dermatrix device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Pyrogen Testing

Software verification and validation testing was conducted, and documentation provided in accordance with FDA's Guidance or the Content of Premarket Submissions for Software Contained in Medical Devices.

Clinical Evidence – N/A. No clinical studies were conducted as part of this submission.

Biocompatibility – Patient contacting materials have been determined to be biocompatible.

Performance Testing - Dermatrix Duo RF Microneedle
The Dermatrix Duo RF Microneedle was subjected to ex-vivo histology testing conducted per the *FDA Guidance to Industry and FDA staff: Premarket Notification (510(k)) submissions for Electrosurgical Devices for General Surgery*. The test consisted of side-by-side histology testing with the Dermatrix Duo (subject device) and the Virtue RF (predicate device). The side-by-side testing demonstrated that the subject device and the predicate device create similar thermal damage when used as intended.

Performance Testing – SFR Non-invasive applicator

The Dermatrix Duo SFR non-invasive applicator was subjected to tissue heating testing to verify its safety and effectiveness for the requested pain relief indication. The testing was performed on 3 subjects with 3 anatomical sites each. The test demonstrated that each handpiece can maintain a therapeutic temperature for at least 10 minutes of treatment.

Conclusion

The Dermatrix Duo and the predicate device have same indication for use, technology, mechanism of actions, operational principles and performance for the proposed indications for use.

The non-clinical data for proposed device, including biocompatibility, bench testing, hardware, and software documentation shows that the device should perform as intended in the specified use. In addition, the Electromagnetic Compatibility and Electrical Safety testing shows that the device is safe.

The comparison between the subject devices and the predicate devices shows that the indication for use and technological characteristic is substantially equivalent although there are some differences, the performance test reports are supported to the substantial equivalence of the subject device, the performance test reports are provided to demonstrate substantial equivalence of the subject devices. Therefore, we conclude that the different characteristics do not raise different questions of safety and effectiveness, and thus the subject devices are substantially equivalent to the predicate devices.