August 27, 2026

VIOL Co., Ltd.
% Jonghyeon Kim
CEO
GMSC Co., Ltd.
B 612, 66, Cheongcho-Ro, Deokyang-Gu, Goyang-Si
Gyeonggi-Do, 10543
Republic Of Korea

Re: K253859
Trade/Device Name: Scarlet Pro (Scarlet Pro)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 29, 2026
Received: July 30, 2026

Dear Jonghyeon Kim:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.08.27 22:23:32 -04'00'

Colin Kejing Chen, 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

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.	K253859

Please provide the device trade name(s).

SCARLET PRO (SCARLET PRO)

Please provide your Indications for Use below.

The SCARLET PRO is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

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

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

510(k) Summary

[As Required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(1)]

11.27, 2025

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Manufacturer: VIOL Co., Ltd.
- Address: C-209-1, 502, 503-1, 503-2, 608, 609, 808, 809, Bundang Technopark C, 744, Pangyo-ro, Bundang-gu, Seongnam-si, Gyeonggi-do (13510), South Korea
- Contact Name: Hyein Yang
- Telephone No.: +82-10-4695-4728
- Email Address: hyein.yang@scarletrf.com
- Registration No.: TBD

3. Identification of Proposed Device(s) [21 CFR 807.92(a)(2)]

510(k) Number	K253859
Trade/Device/Model Name	SCARLET PRO
Product Name	SCARLET PRO
Common Name	Radiofrequency System
Device Classification Name	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number	878.4400
Classification Product Code	GEI
Device Class	Class II
510(k) Review Panel	General & Plastic Surgery

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission is shown as follow;

<Predicate Device #1>

510(k) Number	K180872
Trade/Device/Model Name	SCARLET SRF
Common Name	Radiofrequency System
Device Classification Name	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number	878.4400
Classification Product Code	GEI
Device Class	Class II
510(k) Review Panel	General & Plastic Surgery

<Predicate Device #2>

510(k) Number	K243176
Trade/Device/Model Name	BLESSING SYSTEM
Common Name	Radiofrequency System
Device Classification Name	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number	878.4400
Classification Product Code	GEI
Device Class	Class II
510(k) Review Panel	General & Plastic Surgery

These predicate devices have not been subject to a design-related recall.

5. Description of the Device [21 CFR 807.92(a)(4)]

The SCARLET PRO includes a system main device, a handpiece equitable with a bi-polar electrode, and a foot switch. The RF signal is generated from the main device which is then delivered to the handpiece and then to bi-polar electrode. The RF signal is delivered to the target tissue using penetrating needle electrodes in the consumable tip and S49BS. The bi-polar electrode is placed in light contact with the epidermis while the handpiece is being held at right angles to the target tissue. As the RF signal passes throught the skin, it generates an eletro thermal reaction which is capable of coagulating the tissue. Using the consumable tip and S49BS, SCARLET PRO creates heate within the target skin tissue via needle electrodes from the bi-polar electrode.

6. Indications for Use [21 CFR 807.92(a)(5)]

The SCARLET PRO is intended for use in dermatologic procedures for electrocoagulation and hemostasis.

7. Technological Characteristics (Equivalence to Predicate Device) [21 CFR 807.92(a)(6)]

There are no significant differences in the technological characteristics of these devices compared to the predicate device which adversely affect safety or effectiveness. Provided below is a table summarizing and comparing the technological characteristics of the SCARLET PRO and the predicate device:

[Table 3. Comparison of Proposed Device to Predicate Devices]

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
K Number	-	K180872	K243176	-
Manufacturer	VIOL Co., Ltd.	VIOL Co., Ltd.	Cellah Medical Co., Ltd.	-
Device Name	SCARLET PRO	SCARLET SRF	BLESSING SYSTEM	-
Common Name	Radiofrequency System	Radiofrequency System	Electrosurgical coagulation device and accessories	-
Product Code	GEI	GEI	GEI, OUH	Identical.
Regulation Number	878.4400	878.4400	878.4400	Identical
510(k) Review Panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	Identical
Indications for Use	The SCARLET PRO is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.	The SCARLET SRF is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.	The BLESSING System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis	Identical
Intended for	Prescription Use	Prescription Use	Prescription Use	Identical
RF Output Type	BiPolar	BiPolar	Bipolar/ Monopolar RF	Identical
Electrode No.	25Pin 49Pin	25Pin	DRS Handpiece Tip D-N10 VRS Handpiece Tip V-I49 V-N49	

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
			V-I25 V-N25 V-I16 V-N16 V-CI49 ORS Handpiece Tip O-I1	
Electrode exposure (Depth)	0.5– 3.5 ㎜ (Unit: 0.1)	0.5– 3.5 ㎜ (Unit: 0.25)	vrs mode(bipolar) 0.5 ㎜ ~ 4.0 ㎜ ± 10 %	Similar
Output Control	Foot switch	Foot / ~~Finger switch~~	Foot switch	Similar
Electrode Material	Gold plated (Surgical stainless steel)	Gold plated (Surgical stainless steel)		Identical
No. of usage	Single use	Single use	Single use	Identical
Sterilization	EO gas sterilization	EO gas sterilization	EO gas sterilization	Identical
Spot size	1 cm^2, 1.58 cm^2	1 cm^2		Similar

The 'SCARLET PRO' is substantially equivalent to its predicate devices, the 'SCARLET SRF (K180872)' and the 'BLESSING SYSTEM (K243176)'. All three devices have the same indications for use, RF output type, electrode material, sterilization method, and intended user population. Key technological characteristics—including bipolar output, single-use electrodes, and gold-plated stainless-steel construction—are equivalent across the subject and predicate devices.

The only differences are as follows:

- There are minor differences in output control (foot switch only vs. foot/finger switch), available spot size options, and depth adjustment increments (0.1 mm for SCARLET PRO vs. 0.25 mm for SCARLET SRF). These changes are improvements for user convenience and do not impact the core therapeutic function or overall device safety.

There are no significant differences between the SCARLET PRO and the predicate devices that would adversely affect safety or effectiveness, including for the added 49pin electrode, as confirmed by technological and performance comparison.

In summary, there are no significant differences between the subject and predicate devices that would adversely affect the use of the product. SCARLET PRO is substantially equivalent to both predicate devices in indications for use and technological characteristics.

8. Non-Clinical Test Summary

The 'SCARLET PRO' complies with voluntary standards for electrical safety, electromagnetic compatibility. The following data were provided in support of the substantial equivalence determination:

1) Electrical Safety, Electromagnetic Compatibility and Performance:

The 'SCARLET PRO' complies with the electrical safety and electromagnetic compatibility requirements established by the standards.

Standards No.	Standards Organization	Standard Title	Version	Publication Year
60601-1	IEC	Test for Medical Electrical equipment was performed for General Requirements for basic safety and essential performance	3.2	2020
60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	4.1	2020
60601-2-2	IEC	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	6.1	2023

2) Biocompatibility Testing

The 'SCARLET PRO complies with the bio-compatibility requirements established by the standards.

Standards No.	Standards Organization	Standard Title	Version	Publication Year
10993-5	ISO	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	3.0	2009
10993-10	ISO	Biological evaluation of medical devices - Part 10: Tests for skin sensitization	3.0	2010
10993-11	ISO	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	3.0	2017

3) Software Validation

The 'SCARLET PRO' contains MODERATE level of concern software. The software was designed and developed according to a software development process and was verified and validated. Software information is provided in accordance with FDA guidance:

- The content of premarket submissions for software contained in medical devices, on June 14, 2023

9. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

There are no significant differences between the proposed device and the predicate devices, K180872 and K243176 that would adversely affect the use of the product. It is substantially equivalent to these devices in indications for use and technology characteristics.

10. Conclusion [21 CFR 807.92(b)(3)]

In according with the Federal Food & Drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, concludes that the 'SCARLET PRO' is substantially equivalent in safety and effectiveness to the predicate device as described herein.