April 22, 2020

VIOL Co., Ltd.
Chai kyoung Woo
Manager
C-808, 809 Bundang Technopark C, 744, Pangyo-ro
Bundang-gu, Seongnam-si
Gyeonggi-do, Republic of Korea 13510

Re: K200185
Trade/Device Name: SYLFIRM X
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 17, 2020
Received: January 24, 2020

Dear Chai kyoung Woo:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Long 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200185

Device Name
SYLFIRM X™

Indications for Use *(Describe)*
The SYLFIRM X™ is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

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.

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510(K) Summary

[As Required by 21 CFR 807.92]

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

January 17, 2020

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

- Name of Manufacturer: VIOL Co., Ltd
- Address: C-808, 809, Bundang Technopark C, 744, Pangyo-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, Republic of Korea (13510)
- Contact Name: Chai kyoung Woo
- Telephone No.: +8231-8017-7893
- Email Address: info@celfirm.com
- Registration No.: Awaiting assignment of registration number

3. Trade Name, Regulation Name, Classification [21 CFR 807.92(a)(2)]

Trade/Device Name	**SYLFIRM X™**
Common Name	Radiofrequency System
Regulation Number	21 CFR 878.4400
Regulation Name	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Class	Class II
Product Code	GEI

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

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

1) 510(k) Number: K172023
2) Applicant: Viol Co., Ltd
3) Trade/Device Name: CELFIRM™
4) Regulation Number: 21 CFR 878.4400
5) Regulation Name: Electrosurgical, Cutting & Coagulation & Accessories
6) Regulation Class: Class II
7) Product Code: GEI

1) 510(k) Number: K180872
2) Applicant: Viol Co., Ltd
3) Trade/Device Name: SCARLET SRF
4) Regulation Number: 21 CFR 878.4400
5) Regulation Name: Electrosurgical, Cutting & Coagulation & Accessories
6) Regulation Class: Class II
7) Product Code: GEI

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

The SYLFIRM X™ includes a system main device, a probe equitable with a consumable tip, and a foot switch. The RF signal is generated from the main device which is then delivered to the probe and then to consumable tip. The RF signal is delivered to the target tissue using penetrating needle electrodes in the consumable tip. The consumable tip is placed in light contact with the epidermis while the probe is being held at right angles to the target tissue. As the RF signal passes through the skin, it generates an electro thermal reaction which is capable of coagulating the tissue. Using the consumable tip, SYLFIRM X™ creates heat within the target skin tissue via needle electrodes from the consumable tip.

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

The SYLFIRM X™ is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

7. Determination of Substantial Equivalence

Summary of technological characteristics of the device compared to the predicate device. [21 CFR 807.92(a)(6)]

The SYLFIRM X™ is substantially equivalent to legally marketed predicate devices (CELFIRM™, SCARLET SRF) with respect to indications for use and technology characteristics. The table below presents comparisons between subject device and predicate devices:

[Table 1. Comparison of Proposed Device to Predicate Device]

	Subject Device	Predicate Device	Predicate Device
510(k) Number	-	K172023	K180872
Product Name	SYLFIRM X™	CELFIRM™	SCARLET SRF
Manufacturer	VIOL Co., Ltd.	VIOL Co., Ltd.	VIOL Co., Ltd.
Product Code	GEI	GEI	GEI
Device Class	Class II	Class II	Class II
Indications for Use	The SYLFIRM X™ is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.	The CELFIRM™ 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.
Electrical safety/EMC	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012; IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013; IEC 60601-2-2:2017 IEC 60601-1-2:2014	IEC 60601-1:2005 IEC 60601-1-6:2010 IEC 60601-2-2:2009 IEC 60601-1-2:2007	IEC 60601-1:2005 IEC 60601-1-6:2010 IEC 60601-2-2:2009 IEC 60601-1-2:2007
Input voltage	AC 100-240 V, 50/60 Hz	AC 100-240 V, 50/60 Hz	AC 100-240 V, 50/60 Hz
Operation Type	Coagulation	Coagulation	Coagulation
Foot switch	Yes	Yes	Yes
Tip sterilization method	EO gas	EO gas	EO gas
No. of usage	Single use	Single use	Single use
Dimensions	400 mm(W) x 450 mm(D) x 1580 mm(H)	550 mm(W) x 350 mm(L) x 1220 mm(H)	550 mm(W) x 350 mm(L) x 1220 mm(H)

The SYLFIRM X™ has similar intended uses and technical characteristics to the CELFIRM™, SCARLET SRF Radiofrequency System made by VIOL Co., Ltd. The similarities and differences between the systems are described in the table shown above. In summary, SYLFIRM X™ does not induce any new potential safety risks nor efficacy. We conclude that the SYLFIRM X™ is substantially equivalent to the predicate device.

8. Performance data

Sterilization validation test

To verify the sterility assurance level (10-6) for EO sterilization, the validation and biological indicator (BI) overkill method was used in accordance to ISO 11135-1, ISO 10993-1, ISO 10993-7, ISO 11138-1, ISO 11138-2, ISO 11737-1, ISO 11737-2, AAMI TIR 15, and ISO 13485:2016.

Shelf-life validation test

The tests to validate the shelf life of the device through the proposed shelf life were conducted using the accelerated aging method in accordance to ASTM F1980-07 (2011) Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. The referenced standards for the testing are ISO 11607-1, ISO 11607-2, ISO 11737-2, ASTM F1929, ASTM F 88, and USPNF.

Biocompatibility test

The patient contacting component of the subject device is the Consumable Tip and the biocompatibility tests were in accordance with ISO 10993-4, ISO 10993-5, ISO 10993-7, ISO 10993-10, ISO 10993-11, and USP 39 <151>.

Software validation test

The level of concern of the software (firmware) of the SYLFIRM X™ is moderate and the software validation tests were performed.

EMC & Electrical safety test

The subject device has been evaluated for electromagnetic compatibility and electrical safety testing per applicable standards of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012; IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013; IEC 60601-2-2:2017, CISPR 11:2009/AMD1:2010, IEC 60601-1-2:2014.

Preclinical test

The study was designed to evaluate the safety and effectiveness of SYFLIRM X™ as a radiofrequency(RF) heating device to treat dermal conditions and hemostasis. Three (3) Yucatan Mini-pigs were used in this study. Animal 1501 was euthanized 3 h after treatment on Day 0; Animal 1502 was euthanized on Day 4; and Animals 1503 was euthanized on Day 21.

Treatment with the SYLFIRM X™ device did not result in erythema or edema formation within 1-hour post treatment, nor at any other scheduled timepoints on all animals. The treatment-related microscopic findings consisted of minimal to moderate, multifocal deep dermal collagen necrosis in animals euthanized on Days 0 and 4, and minimal to mild multifocal deep dermal fibrosis on animal euthanized on Day 21.

Test results including histology data demonstrated that the subject device is substantially equivalent to the predicate devices in the market for its intended use.

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

Based on the test results provided in this submission including Sterilization Validation, Shelf life Validation, Biocompatibility, Software Validation, EMC & Electrical Safety Test, and Animal Test, VIOL Co., Ltd. concludes that the SYLFIRM X™ is substantially equivalent to the predicate device as described herein in.