VIOL Co., Ltd.
% Jong Kim
Official Correspondent
GMS Consulting
4th Floor, Digital Cube, 34, Sangamsan-ro, Mapo-gu
Seoul, 03909
Korea, South

Re: K213612
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: May 2, 2022
Received: May 4, 2022

Dear Jong 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 (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,

for

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213612

Device Name
SYLFIRM X™

Indications for Use *(Describe)*
The SYLFIRM X™ is intended for use in dermatologic 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.

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.

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"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

[As Required by 21 CFR 807.92]

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

November 05, 2021

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.: 3009206941

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 878.440
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: K200185
2) Applicant: VIOL Co., Ltd
3) Trade/Device Name: SYLFIRM X™
4) Regulation Number: 21 CFR 878.440
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 hand-piece 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 hand-piece and then to bi-polar electrode. The RF signal is delivered to the target tissue using penetrating needle electrodes in the consumable tip. The bi-polar electrode is placed in light contact with the epidermis while the hand-piece 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 bi-polar electrode.

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

The SYLFIRM X™ is intended for use in dermatologic 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 (SYFLIRM X™(K200185)) 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]

<table>
<tr><th></th><th>Subject Device</th><th>Predicate Device #1</th><th>Remarks</th></tr>
<tr><td>Manufacturer</td><td>VIOL Co., Ltd.</td><td>VIOL Co., Ltd.</td><td></td></tr>
<tr><td>Device Name</td><td>SYLFIRM X™</td><td>SYLFIRM X™</td><td></td></tr>
<tr><td>510(K) No.</td><td>K213612</td><td>K200185</td><td></td></tr>
<tr><td>Product Code</td><td>GEI</td><td>GEI</td><td></td></tr>
<tr><td>Indication for use</td><td>The SYLFIRM X™ is intended for use in dermatologic procedures for electrocoagulation and hemostasis.</td><td>The SYLFIRM X™ is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.</td><td></td></tr>
<tr><td>Input voltage</td><td>AC 100-240 V, 50/60 Hz</td><td>AC 100-240 V, 50/60 Hz</td><td></td></tr>
<tr><td>Output power</td><td>Max 16 W(50 Ω)</td><td>Max 16 W(50 Ω)</td><td></td></tr>
<tr><td>Conduction time</td><td>
<table>
<tr><th>Mode</th><th>Conduction time</th><th>No. of Pulse</th></tr>
<tr><td>CW1</td><td>120 msec</td><td>1</td></tr>
<tr><td>CW2</td><td>160 msec</td><td>1</td></tr>
<tr><td>CW3</td><td>200 msec</td><td>1</td></tr>
<tr><td>CW4</td><td>300 msec</td><td>1</td></tr>
<tr><td>PW1</td><td>120 msec</td><td>4</td></tr>
<tr><td>PW2</td><td>160 msec</td><td>4</td></tr>
<tr><td>PW3</td><td>200 msec</td><td>4</td></tr>
<tr><td>PW4</td><td>240 msec</td><td>4</td></tr>
</table>
</td><td>
<table>
<tr><th>Mode</th><th>Conduction time</th><th>No. of Pulse</th></tr>
<tr><td>CW1</td><td>120 msec</td><td>1</td></tr>
<tr><td>CW2</td><td>160 msec</td><td>1</td></tr>
<tr><td>CW3</td><td>200 msec</td><td>1</td></tr>
<tr><td>CW4</td><td>300 msec</td><td>1</td></tr>
<tr><td>PW1</td><td>120 msec</td><td>4</td></tr>
<tr><td>PW2</td><td>160 msec</td><td>4</td></tr>
<tr><td>PW3</td><td>200 msec</td><td>4</td></tr>
<tr><td>PW4</td><td>240 msec</td><td>4</td></tr>
</table>
</td><td></td></tr>
<tr><td>Output frequency</td><td>2 MHz</td><td>2 MHz</td><td></td></tr>
<tr><td>RF output type</td><td>Bi polar</td><td>Bi polar</td><td></td></tr>
<tr><td>Operation type</td><td>Coagulation</td><td>Coagulation</td><td></td></tr>
<tr><td>Foot switch</td><td>Yes</td><td>Yes</td><td></td></tr>
</table>

<table>
<tr><td colspan="2">Depth</td><td colspan="4">0.3 mm ~ 4.0 mm
(unit: 0.1 mm)</td><td>0.3 mm ~ 4.0 mm
(unit: 0.1 mm)</td><td></td></tr>
<tr><td rowspan="8">TIP</td><td>Sterilization method</td><td colspan="4">EO Gas</td><td>EO Gas</td><td></td></tr>
<tr><td>Disposable</td><td colspan="4">Yes</td><td>Yes</td><td></td></tr>
<tr><td>CONSUMABLE TIP</td><td colspan="4">Provided</td><td>Provided</td><td rowspan="4"></td></tr>
<tr><td>J25BM</td><td colspan="4">Provided</td><td>Not provided</td></tr>
<tr><td>J25BS</td><td colspan="4">Provided</td><td>Not provided</td></tr>
<tr><td>J18BS</td><td colspan="4">Provided</td><td>Not provided</td></tr>
<tr><td rowspan="2">Number of Electrodes</td><td>CONSUMABLE TIP</td><td>J25BM</td><td>J25BS</td><td>J18BS</td><td>Consumable tip</td><td rowspan="2"></td></tr>
<tr><td>25pin (5x5)</td><td>25pin (5x5)</td><td>25pin (5x5)</td><td>18pin (3x6)</td><td>25pin(5x5)</td></tr>
<tr><td rowspan="2">Pitch</td><td>CONSUMABLE TIP</td><td>J25BM</td><td>J25BS</td><td>J18BS</td><td>Consumable tip</td><td rowspan="2"></td></tr>
<tr><td>2.0mm</td><td>2.0mm</td><td>1.5mm</td><td>1.5mm</td><td>2.0mm</td></tr>
<tr><td colspan="2">Dimensions</td><td colspan="4">400 mm(W) x 450 mm(D) x 1580 mm(H)</td><td>400 mm(W) x 450 mm(D) x 1580 mm(H)</td><td></td></tr>
</table>

The SYLFIRM X™ has same intended uses and technical characteristics to the predicate device, SYLFIRM X™(K200185). We performed risk analysis according to the addition of an accessory, and performed necessary verification and validation accordingly. There is no additional consideration for safety and effectiveness, so subject device, SYLFIRM X is substantially equivalent to the predicated 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 J25BM and the biocompatibility tests were in accordance with ISO 10993-5, ISO 10993-10, ISO 10993-11, and USP 38 <661>.

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 G1 was euthanized 3 h after treatment on Day 1; Animal G2 was euthanized on Day 5; and Animals G3 was euthanized on Day 22.

Treatment with the SYLFIRM X™ device did not result in erythema or edema formation within 1-hour post treatment, nor at any other scheduled time points on all animals. The treatment-related microscopic findings consisted of minimal to moderate, multifocal deep dermal collagen necrosis in animals euthanized on Days 1 and 5, and minimal to mild multifocal deep dermal fibrosis on animal euthanized on Day 22.

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

Verification

The bi polar tip (J25BM, J25BS, J18BS) was added without changing the safety or effectiveness of the initially approved equipment, and related performance tests were performed to confirm the same performance. It was confirmed that it has the same performance for additional accessories.

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.