October 13, 2017
VIOL Co., Ltd.
% Priscilla Chung
Regulatory Affairs Specialist
LK Consulting Group USA, Inc.
690 Roosevelt,
Irvine, California 92620

Re: K172023
Trade/Device Name: CELFIRM
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 29, 2017
Received: July 5, 2017

Dear Priscilla Chung:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172023

Device Name

CELFIRM™

Indications for Use *(Describe)*

The CELFIRM™ 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.

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
PRAStaff@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

(K172023)

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: October 12, 2017

1. 510K Applicant / Submitter:

VIOL Co., Ltd.
C-808, 809, Bundang Technopark C,
744, Pangyo-ro, Bundang-gu, Seongnam-si,
Gyeonggi-do (13510), South Korea

Phone : +82-31-8017-7893
Fax : +82-31-8016-7894

2. Submission Contact Person

LK Consulting Group USA, Inc.
690 Roosevelt, Irvine CA 92620
Priscilla Juhee Chung
Phone: 714.202.5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

- Proprietary Name: CELFIRM™
- Common Name: Radiofrequency System
- Classification: 21 CFR 878.4400
  Electrosurgical, Cutting & Coagulation & Accessories
- Product Code: GEI

4. Predicate Device

INFINI Radiofrequency System by Lutronic Corporation (K121481)

5. Description:

The CELFIRM™ includes a system main device, a hand-piece equipped with a tip, and a footswitch. The RF signal is generated from the main device which is then delivered to the hand-piece and then to consumable tip. The RF signal is delivered to the target tissue using penetrating needle electrodes in the tip. The tip 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, CELFIRM™ creates heat within the target skin tissue via needle electrodes from the consumable tip.

6. Indications for Use

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

7. Substantial Equivalence Discussion:

	Proposed Device	Predicate Device
Manufacturer	VIOL Co., Ltd.	Lutronic Corporation
Device Name	CELFIRM™	INFINI Radiofrequency System
510(K) No.	K172023	K121481
Indications for Use	The CELFIRM™ is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.	The INFINI Radiofrequency System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis, and the percutaneous treatment of facial wrinkles.
Electrical Safety/EMC	IEC 60601-1:2005, IEC 6061-1-6:2010, IEC 60601-2-2:2009, EN 60601-1-2:2007, EN 6100-3-2:2006 EN 6100-3-3:2008	IEC 60601-1, IEC 60601-2-2, IEC 60601-1-2
Input Voltage	AC100-240V, 50/60 Hz	AC100-240V, 50/60 Hz
Operation Type	Coagulation	Coagulation
Foot Switch	Yes	Yes
Tip Sterilization Method	EO Gas	EO Gas
Number of Usage	Single use	Single use
Dimensions	550 mm(W) x 350 mm(L) x 1220 mm(H)	362 mm(W) x 409 mm(L) x 1713 mm(H)

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

8. Performance Tests (Non-clinical)

Sterilization Validation, Shelf life Validation, Biocompatibility, Software Validation, EMC & Electrical Safety Test, Max Output Energy, and Animal Test were conducted on the subject device.

Sterilization Validation Test
To verify the sterility assurance level (10^{-6}) for EtO 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 13485:2012.

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 USP-NF <71>.

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 CELFIRM™ is moderate and the software validation tests were performed.

EMC & Electrical Safety Test
The CELFIRM™ has been evaluated for electromagnetic compatibility and electrical safety testing per applicable standards of IEC 60601-1:2005, IEC 6061-1-6:2010, IEC 60601-2-2:2009, EN 60601-1-2:2007, EN 6100-3-2:2006, and EN 6100-3-3:2008, and all the tests met the pre-set criteria.

Max Output Energy
The test on Max Output Energy per Electrode was performed on the subject device to evaluate the max energy per electrode. The test results were compared and evaluated with the standard values of maximum output energy per Electrode of CELFIRM™. The test results met the pre-set criteria and validated the device performance specifications for max energy.

Preclinical Test
This study was designed to evaluate the safety and effectiveness of CELFIRM™ using Yucatan Mini-pigs. Animal were euthanized 3 h after application on Day 1, Day 4, and Day 22. Application with the CELFIRM™ device resulted in transient very slight to well-defined erythema noted within 3-4 h of application but fully resolved by the next Draize evaluation on Day 3. In addition, minimal to mild necrosis was noted in animals euthanized on Days 1 and 5

with the animal euthanized on Day 22 showing dermal fibrosis at the applied sites. There were no other application-related findings.
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. Conclusions:

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