October 11, 2018

VIOl Co., Ltd.
% Mina Joo
Assistant Manager
BT Solutions, Inc.
91-14 Seolleung-ro #402
Gangnam-gu Seoul, Korea 06150

Re: K180872
Trade/Device Name: SCARLET SRF
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 11, 2018
Received: September 13, 2018

Dear Mina Joo:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

FDA

Long H. Chen -S
2018.10.11 07:58:57
-04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180872

Device Name
SCARLET SRF

Indications for Use *(Describe)*
The SCARLET SRF 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:

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Food and Drug Administration
Office of Chief Information Officer
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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."

5. 510(k) Summary

1. General Information

Applicant/Submitter:	VIOL Co., Ltd.
Address:	C-808, 809, Bundang Technopark C, 744, Pangyo-ro, Bundang-gu, Seongnam-si, Gyeonggi-do (13510), South Korea Tel) +82-31-8017-7893 Fax) +82-31-8016-7894
Contact Person:	Mina Joo, BT Solutions, Inc.
Address:	91-14 Seolleung-ro, #402 Gangnam-gu Seoul, 06150 Republic of Korea Tel) +82.2.538.9140 Email) smanager@btsolutions.co.kr
Preparation Date:	September-5-2018

2. Device Name and Code

Device Trade Name:	SCARLET SRF
Common Name:	Radiofrequency System
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Product Code:	GEI
Regulation Number:	878.4400
Classification:	Class II
Review Panel:	General & Plastic Surgery

3. Predicate Devices

Scarlet SRF is substantially equivalent to the following devices

Table 5.1 Predicate devices

Applicant	Device Name	510(k) Number
Lutronic Corporation	INFINI Radiofrequency System	K121481

Table 5.2 Reference devices *

Applicant	Device Name	510(k) Number
Sung Hwan E&B Co., Ltd.	VIVACE Electrosurgical	K150409

*This reference device is referred, of which similarity of having smaller number of non-insulated needles when compare to the same predicate device.

4. Device Description

SCARLET SRF is basically an identical device with the 510(k)-cleared device CELFIRM™ (K172023).

The SCARLET SRF 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, SCARLET SRF creates heat within the target skin tissue via needle electrodes from the consumable tip.

5. Indications / Intended Use

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

6. Technical Characteristics in Comparison to Predicate Devices

SCARLET SRF is substantially equivalent to the following legally marketed predicate devices

	Predicate Device	**Proposed Device**
510(K) Number	K121481	N/A
Manufacturer	Lutronic Corporation	VIOL Co., Ltd.
Device Name	INFINI Radiofrequency System	SCARLET SRF
Clearance Date:	Jun 25,2013	N/A
Classification / Regulation	Class II/21 CFR 878.4400 Electrosurgical, Cutting & Coagulation & Accessories	Class II/21 CFR 878.4400 Electrosurgical, Cutting & Coagulation & Accessories
Product Code	GEI	GEI
Intended Use/ Indications for Use	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.	The SCARLET SRF is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.
Intended for	Prescription Use	Prescription Use
RF Output Type	BiPolar	BiPolar

Electrode exposure (Depth)	0.5– 3.5 mm (Unit: 0.1)	0.5– 3.5 mm (Unit: 0.25)
Output Control	Foot switch	Foot / Finger switch
Electrode Material	Gold plated (Surgical stainless steel)	Gold plated (Surgical stainless steel)
No. of usage	Single use	Single use
Sterilization	EO gas sterilization	EO gas sterilization
Spot size	10 × 10 (mm)	10 × 10 (mm)

7. Performance Data

SCALRET SRF is basically an identical device with the 510(k)-cleared device CELFIRM™.

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 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 SCARLET SRF 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 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 results were passing.

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 the device. The test results met the pre-set criteria and validated the device performance specifications for max energy.

Preclinical Test

The study was designed to evaluate the safety and effectiveness of the subject device as a radiofrequency(RF) heating device to treat dermal conditions and hemostasis. Three (3) Yucatan Mini-pigs were used in this study. Animal 2162 was euthanized 3 h after treatment on Day 1;

Animal 2163 was euthanized on Day 4; and Animals 2164 was euthanized on Day 22. The various treatment sites were then harvested and stored in a 10% NBF prior to histopathology evaluation. During the in-life stage, mortality, clinical observations and body weights were monitored and recorded. In addition, dermal Draize scores were recorded within 3-4 h of treatment, and on Days 3, 5, 13, and 22 in surviving animals.

Treatment with the subject device resulted in transient very slight to well-defined erythema noted within 3-4 h of treatment 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 treatment 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.

8. Substantial Equivalence

The intended use of the SCARLET SRF is within the scope of the predicate device. SCARLET SRF, from both a design and clinical perspective, uses similar or identical technology as the cited predicate device and has the same intended uses. Based upon the predicted overall performance characteristics for the SCARLET SRF, VIOL Co., Ltd., believes that no significant differences exist in usage of its underlying technological principles between SCARLET SRF and the cited predicate device.

9. Conclusions

Based on the information provided in this premarket notification, VIOL Co., Ltd. concludes that the SCARLET SRF is substantially equivalent to the predicate device as described herein.