May 30, 2023

Jiangsu Haize Medical Scientific Development Co., Ltd.
Vincy Gao
RA
No.99, Furongzhongsan Road, Xishan Economical Development
Zone
Wuxi, Jiangsu 214000
China

Re: K230593
Trade/Device Name: Victan
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 9, 2023
Received: May 9, 2023

Dear Vincy Gao:

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.05.30 10:01:30 -04'00'

Mark Trumbore, 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)*
K230593

Device Name
Victan

Indications for Use *(Describe)*
Victan is a sterile, single-patient-use electrosurgical accessory intended to conduct electrosurgical current for cutting and coagulation of tissue and/or to provide suction and irrigation functions to the surgical site.

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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HAIZE MEDICAL Jiangsu Haize Medical Scientific Development Co.,Ltd.

510(K) Summary

——Single Use Surgical Electrocoagulator

Compiled by: Vincy Gao Date: 2023.01.02

Reviewed by: Zhang Rong Date: 2023.01.16

Approved by: Qian Jianmin Date: 2023.02.15

Jiangsu Haize Medical Scientific Development Co.,Ltd

HAIZE MEDICAL Jiangsu Haize Medical Scientific Development Co.,Ltd.

510(k) Summary

1. Submitter Information

Applicant/Submitter:	Jiangsu Haize Medical Scientific Development Co.,Ltd. No.99, Furongzhongsan Road, Xishan Economical Development Zone, Wuxi, Jiangsu, China Phone: 086-0510-82833301 Fax: 086-0510-82833301
Contact Person:	Vincy Gao chenll@haizemed.net

2. Device

Trade Name	Victan
Common Name	Single Use Surgical Electrocoagulator
Classification Name	Electrosurgical, cutting & coagulation device & accessories
Regulation Number	21 CFR 878.4400
Device Class	Class II
Product Code	GEI
510(K) Number	K230593

3. Predicate Device

Manufacturer	Product Name	510(K) Number
Sejong Medical Co., Ltd.	LAP-iX	K173112

4. Device Description

The Single Use Surgical Electrocoagulator is a sterile, single-patient-use electrosurgical accessory, and deliver electrical current from high-frequency generator to the surgical site. At the same time ,

the product can also provides suction or irrigation by connecting to a negative pressure drainage device. The proposed product consists of Electrode, External tube, Irrigation and suction tube, External tube control button, Rotator, Irrigation switch, Suction switch, Handle, Suction connecting tube, Suction connector, Irrigation connector, Cable, Irrigation connecting tube, Outer tube.

Single Use Surgical Electrocoagulator should be operated with HF generators having a nominal frequency of the HF voltage between 300 kHz and 3 MHz. Lower frequencies may cause nerve stimulation and thus uncontrolled convulsion. In case of higher frequencies, user/patient safety cannot be guaranteed because insulation may heat up so that dielectric strength is no longer given. All equipment conforming to this specs can be used.

The product was sterilized by EO. The valid period of sterilization was 3 years.

5. Indications for Use

Single Use Surgical Electrocoagulator is a sterile, single-patient-use electrosurgical accessory intended to conduct electrosurgical current for cutting and coagulation of tissue and/or to provide suction and irrigation functions to the surgical site.

6. Comparison of Technological Characteristics with the Predicate Device

Item	Proposed Device	Predicate Device	Equivalence
Trade Name	Victan	LAP-iX	/
Manufacturer	Jiangsu Haize Medical Scientific Development Co.,Ltd.	Sejong Medical Co., Ltd.	/
Classification Name	Electrosurgical, cutting & coagulation device & accessories	Electrosurgical, cutting & coagulation device & accessories	Same
510(K) Number	K230593	K173112	/
Device Class	Class II	Class II	Same
Product Code	GEI	GEI	Same
Regulation Number	21 CFR 878.4400	21 CFR 878.4400	Same
Indications for Use	Single Use Surgical Electrocoagulator is a sterile, single-patient-use electrosurgical accessory intended to conduct electrosurgical current for cutting and coagulation of tissue and/or to provide suction and irrigation functions	Single Use Surgical Electrocoagulator is a sterile, single-patient-use electrosurgical accessory intended to conduct electrosurgical current for cutting and coagulation of tissue and/or to provide suction and irrigation functions	Same

	to the surgical site.	to the surgical site.	
Energy Type	Radiofrequency	Radiofrequency	Same
Electrode Type	Monopolar	Monopolar	Same
End-tip Type	Angle, Spade, Hook, Needle	L-hook,Spoon	Different (After the assessment, End-tip type does not affect electrical safety or performance.)
Handle Type	Pistol Type, Trumpet Type	Pistol Type, Trumpet Type	Same
Length	Function Tube Length:190/335/435mm	Tip Length:37/48cm	Different (After the assessment, End-tip type does not affect electrical safety or performance.)
Materials(Electrode)	Stainless steel	Stainless steel	Same
Sterilization	EO	EO	Same
Performance Test	Appearance, Dimension, Leakage, Pressure Resistance, Continuity, Irrigation and Suction Flow, Tensile Strength, Electrical safety and electromagnetic compatibility (EMC)	Nominal size, Leakage, Continuity, Dielectric Strength Test of Electrode cable, HF Leakage current Test of Electrode cable, and Tensile Strength Test of Electrode cable	Equivalent (The actual test results are the same.)

7. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

7.1. Biocompatibility

The device has been evaluated for its biological safety according to ISO10993-1 Biological Evaluation of Medical Devices - Part 1:Evaluation and Testing Within a Risk Management Process. Following endpoints have assessed during the evaluation:

* Cytotoxicity
* Sensitization
* Intracutaneous Reactivity
* Acute Systemic Toxicity
* Material-Mediated Pyrogenicity

7.2. Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Single Use Surgical Electrocoagulator. The subject device complies with relevant clauses of the IEC 60601-1, IEC-60601-2-2 standards for safety and the IEC 60601-1-2 for EMC.

7.3. Sterilization

The subject device and the predicate device are sterilized via Ethylene Oxide; both devices are sterilized to the same sterility assurance level.

7.4. Shelf-life

Accelerated Aging testing confirmed that the expiration date of subject device is 3 year from the manufacturing date.

7.5. Bench Testing

Haize Medical conducted bench testing to ensure that the design of Single Use Electrocoagulator applicable the specifications and that the product is safety and effective in use.

Test included:

- Appearance
- Dimension
- Leakage
- Pressure Resistance
- Continuity
- Irrigation and Suction Flow
- Tensile Strength

7.6. Animal Study

This premarket notification does not rely on preclinical animal testing to demonstrate substantial equivalence.

7.7. Clinical Study

This premarket notification does not rely on human clinical trial data to demonstrate substantial equivalence.

8. Substantial Equivalence

The subject and predicate device have the same fundamental technology and indications for use. The performance, dimensions and materials of the subject device are similar to the predicate device. Although there some minor differences with each product, these differences between the subject device and the predicate device do not raise new or different questions of safety and efficacy. There is no new technology and no difference that would raise new or different questions of safety or efficacy.

9. Conclusion

The subject device are identical in intend use, indications and technology compared to the predicate device. The results of the test demonstrate that the subject devices do not raise new questions of safety and effectiveness and are substantially equivalent to the predicate devices.