March 6, 2024

Jiangsu Hope Biomedical Science&Technology Co., Ltd.
℅ Kitty Zhang
Regulation Affair Staff
Shanghai Jiushun Enterprise Management Technology Service Co
15 floor, 25 floor,Bao An Tower,No.800
Dongfang Road
Shanghai, Shanghai 200122
China

Re: K232703
Trade/Device Name: Disposable Bipolar Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 31, 2024
Received: February 2, 2024

Dear Kitty Zhang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2024.03.06 13:48:41 -05'00'

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.

Submission Number *(if known)*

K232703

Device Name

Disposable Bipolar Forceps

Indications for Use *(Describe)*

Disposable Bipolar Forceps are single use devices sold sterile and are intended for use in electrosurgery for coagulation of tissue.

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.

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510(k) Summary

March 6, 2024

1. Submitter Information

Company Name: Jiangsu Hope Biomedical Science&Technology Co.,Ltd.

Address: No.3 Building, Hi-tech Innovation Service Center, Jiangdu District, Yangzhou City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

Applicant Contact: Shaote Geng

Applicant Contact Telephone: +86-514-87185186

Applicant Contact Email：shaote.geng@hoboat.com

Correspondent Name：Shanghai Jiushun Enterprise Management Technology Service Co., Ltd.

Correspondent Address：15 floor,25 floor,Bao An Tower,No.800,Dongfang Road, Shanghai, China. Shanghai Shanghai 200122 China

Correspondent Contact: Mrs. Kitty Zhang

Correspondent Contact Telephone: +86-21-50931939

Correspondent Contact Email: kitty-zhang@isosh.com

Correspondent Contact Telephone: +86-21-50931939

2. Subject Device Information

Common Name: Electrosurgical cutting and coagulation device and accessories

Trade Name: Disposable Bipolar Forceps

Model: ZKN-3CWZ

Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories

Review Panel: General and Plastic Surgery

Product Code: GEI

Regulation Number: 21 CFR 878.4400

Regulation Class: II

3. Predicate Device Information

Sponsor: Synergetics, Inc.

Common Name: Electrosurgical Instrumentation

Trade Name: Synergetics Disposable Spetzler-Mails Standard Bipolar Forceps

510(k) number: K121426

Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories

Review Panel: General and Plastic Surgery

Product Code: GEI

Regulation Number: 21 CFR 878.4400

Regulation Class: II

4. Device Description Summary

1) The mechanism of action

The mechanism of action of Disposable Bipolar Forceps are to hemostasis of tissue by bipolar electrocoagulation. The Disposable Bipolar Forceps can carry out electrocoagulation of tissues. The tissue is grasped between the forceps tips, each of which acts as an electrode, and current passes to desiccate and coagulate the tissue.

2) Mechanical structure

Disposable Bipolar Forceps consists of forceps pieces, forceps holder, wire. The tail end of the forceps pieces are connected with the forceps holder. The forceps holder is

provided with a high frequency input wire, and the wire can be connected with the high frequency surgical equipment through a plug. The outer surface of the forceps pieces are provided with an insulation layer.

Disposable Bipolar Forceps materials: forceps tips material: silver plated brass; forceps pieces material: brass; forceps pieces coating: epoxy resin; packaging: PETG tray, Tyvek lid.

3) Principle of operation and technological characteristics

The structure of Disposable Bipolar Forceps is double forceps pieces. Two fingers pinch the left and right forceps pieces, so that the forceps tips gently clamp the tissues, through the high frequency current to achieve electrocoagulation hemostasis. The rebound action is realized by the rebound force of the forceps pieces.

4) Operating procedures

Disposable Bipolar forceps are connected with the bipolar output of an electrosurgical generator. Disposable Bipolar forceps must only be used with bipolar coagulation current. The bipolar forceps must be operated with the following parameters: Rated Accessory Voltage is 500Vpk.

5. Indications for Use

Disposable Bipolar Forceps are single use devices sold sterile and are intended for use in electrosurgery for coagulation of tissue.

6. Substantial Equivalence Discussion

1)General Comparison

Elements of Comparison	**Subject Device**	**Predicate Device K121426**
Company	Jiangsu Hope Biomedical Science&Technology Co.,Ltd.	Synergetics, Inc.

Device Name	Disposable Bipolar Forceps	Synergetics Disposable Spetzler-Mails Standard Bipolar Forceps
Model	ZKN-3CWZ	Disposable Spetzler-Malis Standard Bipolar Forceps
Prescription/OTC	Prescription	Prescription
Regulation Number	21 CFR 878.4400	21 CFR 878.4400
Code	GEI	GEI
Class	II	II
Indication for Use	Disposable Bipolar Forceps are single use devices sold sterile and are intended for use in electrosurgery for coagulation of tissue.	The Synergetics Disposable Spetzler-Mails Standard Bipolar Forceps are single use devices sold sterile and are intended for use in electrosurgery for coagulation of tissue.
Single Use	Yes	Yes
Device design	Bayonet Style	Bayonet Style
Length	205mm	180mm, 200mm, 230mm
Tip Size	1.2mm	0.5 mm, 1.0 mm, 1.5 mm
Color	Yellow	Yellow
Tips material	Silver plated	Silver plated
Electrical Safety Testing	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2
Biocompatibility	Cytotoxicity Sensitization Intracutaneous Reactivity Acute systemic toxicity test Pyrogenicity test	Biocompatible Silver plated Aluminum base with PVDF insulation
Sterility	Yes	Yes
Sterilization Method	Ethylene oxide	Ethylene oxide
Shelf Life	3 years	5years
Packaging	Rigid PETG Tray, Tyvek lid	Rigid PETG Tray, Tyvek lid

2) Indication for Use Comparison

Indication for use of the subject device: Disposable Bipolar Forceps are single use devices sold sterile and are intended for use in electrosurgery for coagulation of tissue.

Indication for use of the Equivalence: The Synergetics Disposable Speztler-Malis Standard Forceps are single use devices sold sterile and are intended for use in electrosurgery for coagulation of tissue.

The indication for use of subject device and the Equivalence is same.

3) Technological Comparison

Based on available 510(k) information provided herein, Disposable Bipolar Forceps is similar to the predicate devices in terms of material, technology, design and performance specifications.

7. Non-Clinical Tests Summary

EMC, electrical safety, biocompatibility and sterility were evaluated according to recognized standards listed above.

To demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified, we follow the Premarket Notification (510(k) Submissions for Electrosurgical Devices for General Surgery Guidance for Industry and Food and Drug Administration Staff.;

Ex-vivo experimental study on Thermal Effects, was conducted follow Premarket Notification (510(k) Submissions for Electrosurgical Devices for General Surgery Guidance for Industry and Food and Drug Administration Staff which refer to Ex-vivo experimental study on Thermal Effects of Disposable Bipolar Forceps;

and Mechanical Strength.

Conclusion:

The subject device Disposable Bipolar Forceps is similar by technological specifications and intended use to the predicate device. Performance testing results shows that differences do not affect the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate device for requested indications for use.