December 5, 2023

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: K231615
Trade/Device Name: Disposable Endoscopic Bipolar
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 6, 2023
Received: November 6, 2023

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: 2023.12.05 13:25:49 -05'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices

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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)*
K231615

Device Name
Disposable Endoscopic Bipolar

Indications for Use *(Describe)*
Disposable Endoscopic Bipolar is a sterile, single use electrosurgical instrument intended to conduct electrosurgical current for coagulation of tissue during general surgical procedures.

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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510(k) Summary

1. Submitter Information

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

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Correspondent Contact: Mrs. Kitty Zhang

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2. Subject Device Information

Common Name: Electrosurgical cutting and coagulation device and accessories

Trade Name: Disposable Endoscopic Bipolar

Model: WZX-8XZWZ、WZX-8CZWW

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: Günter Bissinger Medizintechnik GmbH

Common Name: Electrosurgical Instrumentation

Trade Name: Bipolar Micro-Coagulation Forceps

510(k) number: K172368

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 Summay

1). the mechanism of action The mechanism of action of disposable endoscopic bipolar is to hemostasis of tissue by bipolar electrocoagulation. The disposable endoscopic bipolar can carry out more precise electrocoagulation and treatment of small blood vessels and other structures. The principle of disposable endoscopic bipolar is that the electrosurgical current is released through the two electrode tips, so that the human tissue between the electrode tips of the disposable endoscopic bipolar produces the thermal effect to coagulate proteins in the blood to achieve hemostasis. Due to the mutual insulation of the two electrodes of the disposable endoscopic bipolar, only the electrode tips conduct current. During electrocoagulation, the current passes from one electrode tip to the other, and the tissue between the two electrode tips is affected by the thermal effect, while the

tissue outside the electrode tips is little or not affected, which has a protective effect on the tissue.

2). mechanical structure Disposable endoscopic bipolar consists of electrode, power line, socket, handle group, inner rod, pushrod. Handle group consists of block, set screw, handle, fixed block, rivet pin, rivet cap, connecting rod, sliding block, spring, front insert, upper cover, lower cover, tail sleeve. The inner rod is set in the pushrod and handle group mechanism, and is fixed with set screws and fixed block, and the pushrod is connected to the sliding block. The back end of the push rod is shaped like a semi-circle for easy bending and use. The product is divided in straight and curved based on poshrod shape type. The electrodes are equipped with the insulating sleeve, and the outer side of the sleeve is provided with a stainless steel armor plate to prevent the push rod from rubbing the sleeve. The electrodes are fixed in the inner rod. The electrodes are connected to the socket through power line, and the socket can be connected to the high frequency surgical equipment. Disposable endoscopic bipolar materials: Stainless Steel, Plastic Material.

3). principle of operation and technological characteristics The handle group mechanism of the disposable endoscopic bipolar is a two-finger hand pinch connecting rod structure, and the rebound action is realized by the spring rebound force. Principle of operation: When kneading the handle, the two connecting rods push the sliding block and the pushrod forward, the pushrod pushes the electrode to achieve the clamping action, and then the hand is loosened, and the sliding block is pushed back by the spring, and the electrode is opened by its own elasticity, so that the closure and opening of the electrode are realized. Technological characteristics: Rated Accessory Voltage is 500Vpk. The external diameter of the pushrod is 3.2mm, working length is 175mm. Electrode tips width are 0.5-1.2mm. 4). operating procedures The disposable endoscopic bipolar specifications should be selected according to the clinical needs. Take the sterile pack, tear up and take out the disposable endoscopic bipolar, connect the product to high frequency device

with special connection, the tissue attachments on the electrode tips could be removed with gauze during surgery. Disposable endoscopic bipolar has to be connected to bipolar receptacle of OBS Electrosurgical Generator (Model: OBS-350A) of Baisheng Medical Co.,Ltd. Aseptic operation and related procedures should be strictly followed, also kindly observe the patient signs during surgery. This product should be used by professional medical staff.

5. **General Comparison**

Elements of Comparison	**Subject Device**	**Predicate Device**	**Result**
Company	Jiangsu Hope Biomedical Science&Technology Co.,Ltd	Günter Bissinger Medizintechnik GmbH	/
Device Name	Disposable Endoscopic Bipolar	Bipolar Micro-Coagulation Forceps (K172368)	/
Model	WZX-8XZWZ, WZX-8CZWW	POWERGRIP 3.0, MITHRAS	/
Prescription/OTC	Prescription	Prescription	Same
Regulation Number	21 CFR 878.4400	21 CFR 878.4400	Same
Code	GEI	GEI	Same
Class	II	II	Same
Indication for Use	Disposable Endoscopic Bipolar is a sterile, single use electrosurgical instrument intended to conduct electrosurgical current for coagulation of tissue during general surgical procedures.	The Bipolar Micro-Coagulation Forceps are intended to remove tissue and control bleeding.	Similar Note1

Single Use	Yes	No	Different Note 2.
Device design	Disposable endoscopic bipolars are electrosurgical tools available with different handles and different tip designs.	Bipolar Micro-Coagulation Forceps are electrosurgical tools available with different handles and different tip designs.	same
Length	WZX-8CZWW, WZX-8XZWZ: 320±50mm；	30cm	Similar Note 3
Tip Size	1.2±0.3mm	0.35 – 2.8 mm	Similar Note 4
Color	Black	Black	Same
Tips material	Medical Stainless Steel	Stainless Steel	Same
Maximum peak Voltage(Vp)	500±10%	300	Different Note 5
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	Same
Biocompatibility	Cytotoxicity Sensitization Intracutaneous Reactivity Acute systemic toxicity test Pyrogenicity test	Cytotoxicity Sensitization Irritation or Intracutaneous Reactivity	Different Note 6
Sterility	Yes	Non-sterile, reusable	Different Note 7
Sterilization Method	Ethylene oxide	NA	Different Note 7
Shelf Life	3 years	NA	Different Note 8

Based on available 510(k) information provided herein, Disposable Endoscopic Bipolar is considered substantially equivalent to the predicate devices in terms of indications for use, material, technology, design and performance specifications. The performed tests show that the subjected device is in compliance with the applicable recognized standards. Performed comparison testing with the predicate device shows substantial equivalence to the FDA-cleared predicate device Sponsor: Jiangsu Hope Biomedical Science&Technology Co.,Ltd Subject Device: Disposable Endoscopic Bipolar Bissinger Medizintechnik GmbH Bipolar Micro-Coagulation Forceps (K172368). There are no differences between the devices which would raise new issues of safety or effectiveness. The Bipolar Micro-Coagulation Forceps is substantially equivalent to predicate device Bissinger Medizintechnik GmbH Bipolar Micro-Coagulation Forceps (K172368).

6. **Non-Clinical and/or Clinical Tests Summary & Conclusions**

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, and Factory Inspection Instruction for Disposable Endoscopic Bipolar, to conduct the performances bench tests, details please refer to Performance Bench Test Report;

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 Endoscopic Bipolar; and Mechanical Strength (refer to Mechanical Strength Verification Report,included in the EMC, Wireless, & EMT Documentation attachments).

Conclusion:

The subject device Disposable Endoscopic Bipolar has all features of the predicate device based on its intended use, The few differences do not affect the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate device.