December 14, 2023

Beijing ZKSK Technology Co., Ltd
℅ Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801,No.161,East Lujiazui Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K231721
Trade/Device Name: Disposable Hot Biopsy Forceps
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: KGE
Dated: October 21, 2023
Received: November 13, 2023

Dear Boyle Wang:

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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology 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)*
K231721

Device Name
Disposable Hot Biopsy Forceps

Indications for Use *(Describe)*
This instrument has been designed to be used with endoscopes to collect tissue,cauterize,coagulate and perform hemostasis using high-frequency current within the digestive tract.

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

K231721

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's Information

Name: Beijing ZKSK Technology Co., Ltd
Address: Building 9, 6 & No.6 Yuan Hengye North 7th Street, Yongle Economic Development Zone, Tongzhou District,Beijing 101105, China
Tel: +86 -13811778090
Contact: Ma Li

Designated Submission Correspondent

Contact: Mr. Boyle Wang
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Tel: +86-21-50313932
Email: Info@truthful.com.cn

2.0 Device Information

Trade name: Disposable Hot Biopsy Forceps
Common name: Forceps, Biopsy, Electric

3.0 Classification

Production code: KGE
Regulation number: 21 CFR 876.4300
Regulation name: Endoscopic electrosurgical unit and accessories

Classification: Class II
Panel: Gastroenterology/Urology

4.0 Predicate Device Information

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
Trade/Device Name: Electrosurgical Hemostatic Forceps Series
510(k) number: K062517

5.0 Device Description

The subject device Disposable Hot Biopsy Forceps is a sterile, single-use endoscopic device, intended to be used with endoscopes to cut, coagulate and stop bleeding in the digestive tract by using high-frequency current.
The disposable Hot Biopsy Forceps consists of an insertion part and a handle part. The insertion part includes a jaw assembly and a spring tube; the handle part includes a handle, a finger ring, a conductive column, a rotating sleeve, a locking sleeve, and a sheath tube.
The subject device has 7 specifications. The differences among these models are the jaws type, Jaw O.D, and Working Length.
The subject device is EO sterilized to achieve the Sterility Assurance Level (SAL) of 10^{-6} and placed in a sterility maintenance package to ensure a shelf life of 3 years.

The materials used for construction of Disposable Hot Biopsy Forceps are typical for this type of medical device. Materials of Jaw and spring tube is stainless steel SUS304, the Sheath tube is made of HDPE, the Locking sleeve, Rotating sleeve and handle are made of ABS. The conductive column is made of H62.

6.0 Indication for Use Statement

This instrument has been designed to be used with endoscopes to collect tissue, cauterize, coagulate and perform hemostasis using high-frequency current within the digestive tract.

7.0 Summary of Non-Clinical Testing

Summary of non-clinical and performance testing- Bench testing was performed to evaluate the performance and functionality of the subject device against requirement specification. The subject device has been subjected to compliance testing according to, by FDA, recognized consensus standards ISO 10993-1, ISO 10993-7, ISO 11607-1, and Technical Requirements of “Disposable Hot Biopsy Forceps” provided by Beijing ZKSK Technology Co., Ltd. Results from testing performed confirms that the design requirement specification and user needs have been met. The subject device is confirmed to be safe and effective for the intended use.

7.1 Sterilization and shelf life of Disposable Hot Biopsy Forceps is delivered sterile and have successfully been tested according to ISO 11135 and ASTM 1980. The label shelf life is 3 years.
7.2 Biocompatibility testing of Disposable Hot Biopsy Forceps has successfully been

tested for cytotoxicity, sensitization, intracutaneously irritation, acute systemic toxicity and material medicated pyrogenicity. The test results verify that the biocompatibility criteria given in ISO 10993 are fulfilled. Disposable Hot Biopsy Forceps is non-toxic and biocompatible.

7.3 Performance testing – Bench: The performance of Disposable Hot Biopsy Forceps has been verified. Tests as described in table 1 have been completed.

Table 1: Performance testing summary – Bench

Test Item	Description
Appearance	To confirm that subject device is integrity and cleanliness and hygiene.
Dimension	To confirm that the dimensions of the subject device complied with the company's requirements.
Rotation performance	With smooth rotation and without interference.
Pushability Testing	To evaluate the ease and smoothness with which the forceps can be advanced or pushed through the working channel of an endoscope.
Actuation Testing	To evaluate the functionality and performance of the forceps' actuation mechanism. Actuation testing ensures that the forceps can be properly opened and closed, allowing for effective tissue sampling during endoscopic procedures.
Hemostatic Performance Testing	To assess their ability to achieve hemostasis effectively after tissue sampling during endoscopic procedures.
Compatibility testing with endoscopes	The hot biopsy forceps can be freely inserted into the orifice of the corresponding specification of the endoscope, without no sense of distortion or resistance.
Conduction resistance	The resistance between the hot biopsy forceps connector and the forceps head assembly shall be $\leqslant$ 30Ω.
Sterility	This device is sterilized by ethylene oxide. The device shall be sterile.
EO residue	EO residue shall be $\leqslant$10μg/g.

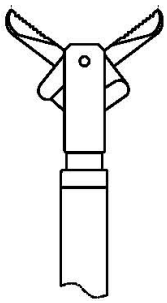
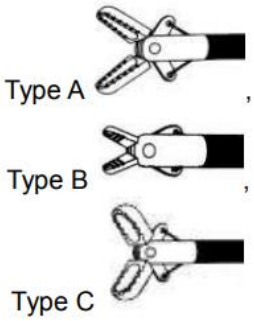
7.4 Electromagnetic Compatibility and Electrical Safety: Tests on Electromagnetic Compatibility and Electrical Safety were performed in accordance to requirements per IEC 60601-1:2005+A1:2012 and IEC 60601-2-2:2017.

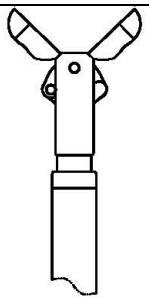
8.0 Summary of Clinical Testing

No clinical study is included in this submission.

9.0 Technological Characteristic Comparison Table

Table 2- Comparison of Technology Characteristics

Item	Subject Device	Predicate Device
510(k) No.	K231721	K062517
Product Code	KGE	KGE
Regulation No.	21 CFR 876.4300	21 CFR 876.4300
Class	II	II
Intended Use/Indication for Use	This instrument has been designed to be used with endoscopes to collect tissue, cauterize, coagulate and perform hemostasis using high-frequency current within the digestive tract.	FD-1L/U-1 Hot Biopsy Forceps This instrument has been designed to be used with Olympus endoscopes to collect tissue, cauterize, coagulate and perform hemostasis using high-frequency current within the digestive tract. FD-410LR Single Use Electrosuraical Hemostatic Forceps This instrument has been designed to be used with Olympus endoscopes to cauterize, coagulate and perform hemostasis using high-frequency current within the digestive tract.
Minimal working channel	2.8mm	2.8mm
Sheath OD.	2.4mm,1.8mm	2.4mm,1.8mm
Working Length	1600mm,1800mm,2000mm, 2300mm	1650mm, 1950mm and 2300mm
Jaws Type	Pointed type:  Standard type:	

		
Energy Used/Delivered	Monopolar Radio Frequency Current	Monopolar Radio Frequency Current
Rated High-Frequency Voltage	Cutting—1600Vp; Coagulation—2100Vp	COAG :2900Vp-p
Materials of Construction	Materials of Jaw and spring tube is stainless steel SUS304, the Sheath tube is made of HDPE, the Locking sleeve, Rotating sleeve and handle are made of ABS. The conductive column is made of H62.	Not publicly available
Opening Width	Pointed type:7mm Standard type:6mm	5mm
Sterile	Ethylene Oxide, SAL: 10^{-6}	Ethylene Oxide, SAL: 10^{-6}
Shelf Life	3 years	3 years
Single Use	Single Use	Single Use
Performance Comparison testing	The test was conducted to the predicate device and current device to compare their performance including device Rotation performance, Pushability Testing, Actuation Testing, Hemostatic Performance, Conduction resistance and Compatible endoscopes tests.	
Biocompatibility	Conform with ISO10993-1 (ISO10993-5, ISO10993-10, ISO10993-11)	Conform with ISO 10993 -1 standards
Electromagnetic Compatibility and Electrical Safety	Conform with IEC 60601-1:2005+A1:2012 and IEC 60601-2-2:2017	Conform with IEC60601-1 and IEC 60601-2-2.

10.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the

proposed device is as safe, as effective, and performs as well as the legally marketed predicated device in K062517 and raises no new questions of safety or effectiveness. The differences between both devices are insignificant in terms of safety and effectiveness.