March 27, 2020

Zhejiang Chuangxiang Medical Technology Co., LTD.
Lucius Long
RA Manager
301B, No. 22, XinYan Road
Hanzhou, 311100
CHINA

Re: K191900
Trade/Device Name: Single Use Grasping Forceps
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCZ
Dated: February 25, 2020
Received: February 25, 2020

Dear Lucius Long:

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,

Shanil P. Haugen, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191900

Device Name
Single Use Grasping Forceps

Indications for Use *(Describe)*
Single Use Grasping Forceps are indicated for use in gastrointestinal tract of the patient to grasp, clip, drag, and remove tissue or foreign particle during endoscopic 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Zhejiang Chuangxiang Medical Technology Co.,Ltd

Section 2 510(k) Summary(21CFR 807.92)

1. Submitter's information

Name: Zhejiang Chuangxiang Medical Technology Co., LTD.

Address: 301B, No.22, XinYan Road Yuhang Economic And Technological Development Zone Hangzhou Zhejiang China

Contact person: Lucius.Long
Telephone: 86-571-89167088
Fax: 86-571-89167086

2. Device

Name of the device: Single Use Grasping Forceps
Classification name: Endoscope and Accessories per 21 CFR 876.1500
Regulation class: 2
Regulation number:876.1500
Panel: Gastroenterology/Urology
Product code: OCZ

3. Predicative device

3.1) 510(k) Number: K152802,
Product Name: Grasping Forceps
3.2) 510(k) Number: K120084,
Product Name: The US Endoscopy Endoscopic Retrieval Device

4. Device description

The proposed device Single Use Grasping Forceps is a sterile, single-use device, designed to pass through a 2.0mm and 2.8mm or greater working channel of an endoscope. The main components of Single Use Grasping Forceps are jaws, spring sheath and handle. This device can be used to grasping tissue and/or retrieve foreign bodies, and excised tissue through jaws open and close. The Single Use Grasping Forceps has three models, the differences of these models are type of jaws, OD of the device and working length.

The proposed devices are 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.

5. Indications for use

Single Use Grasping Forceps are indicated for use in gastrointestinal tract of the patient to grasp, clip, drag and remove tissue or foreign particle during endoscopic procedures.

6. Technological Characteristics

The Single Use Grasping Forceps incorporates substantially equivalent device materials, design, configuration, packaging fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate devices. It determined to be Substantially Equivalent to the predicate devices.

Comparison to predicate Devices:

Item	Proposed device	Primary Predicate device	Additional Predicate device	Comparison to Predicate Devices
Device name	Single Use Grasping Forceps	Grasping Forceps	The US Endoscopy Endoscopic Retrieval Device	/
510(k) number	K191900	K152802	K120084	/
Manufacturer	Zhejiang Chuangxiang Medical Technology Co., LTD.	MICRO-TECH (NANJING) CO., LTD.	UNITED STATES ENDOSCOPY GROUP, INC.	/
Product Code	OCZ	OCZ	OCZ	Same
Regulation No.	876.1500	876.1500	876.1500	Same
Class	2	2	2	Same
Indications for Use	Single Use Grasping Forceps are indicated for use in gastrointestinal tract of the patient to grasp, clip, drag and remove tissue or foreign particle during endoscopic procedures.	Grasping Forceps device is intended to be used to grasp tissue, retrieve foreign bodies, and remove tissue from within the gastrointestinal tract.	The US Endoscopy Endoscopic Retrieval Device is intended to be used to grasp tissue and/or retrieve foreign bodies, excised tissue and stents during endoscopic procedures.	Similar

Supplied Sterile	Yes	Yes	Yes	Same
Sterilization method	EO	EO	EO	Same
Jaws open wide	4.5mm, 8.5mm, 7mm,8.2mm	6.3mm,8.1mm	10mm	Similar
Working Length	1800mm, 2300mm	1800mm,2300mm	2300mm	Similar
Configuration	Jaws, Spring sheath, Finger ring	Jaws, Spring sheath, Finger ring	Jaws, Spring sheath, Finger ring	Same
Single Use	Yes	Yes	Yes	Same
Packaging	Single-use EO sterilized pouch with one device per pouch	Single-use EO sterilized pouch with one device per pouch	Single-use EO sterilized pouch with one device per pouch	Same
Shelf Life	Three years	Five years	Three years	Similar

7. Performance data

The devices Single Use Grasping Forceps has undergo performance test bench and compared with the predicate device, the results are all meet the requirements.
The following bench tests were performed on the Single Use Grasping Forceps:
Appearance;
Dimension;
Jaws open wide;
The Grasping jaws opened and closed performance and compatibility with endoscope channel;
Handle to core wire tensile strength;
Clamping strength;
Jaws misalignment test.
The testing performed demonstrated that the proposed and predicate devices are substantial equivalent.

The EO residual was measured after sterilization of the device to meet the criteria defined in ISO 11135 Second edition 2014 and ISO 10993-7 Second Edition 2008-10-15. The shelf-life for three years had been validated in accelerated testing according to ASTM F1980-16 (2016) and the requirements on packaging for terminally sterilized medical device per ISO 11607-1 First Edition 2006-04-15 and ISO 11607-2 First Edition 2006-04-15 are also met. The testing successfully demonstrated essential performance is achieved before and after the shelf life test.

Biocompatibility testing was performed in accordance with the FDA Guidance," Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" issued on June 16, 2016. The cytotoxicity, sensitization and intracutaneous irritation test were performed to demonstrate the biocompatibility of the device.

8. Non-Clinical Test Conclusion:

Non clinical tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent(SE) to the predicate device.
The test results demonstrated the proposed device complies with the following standards:
EN868-5:2018, Packaging for terminally sterilized medical devices-Part 5: Sealable pouches and reels of porous materials and plastic film construction- Requirements and test methods.
ASTM F88/F88M-15, Standard Test Method For Seal Strength Of Flexible Barrier Materials.
ASTM F1929-15, Standard Test Method For Detecting Seal Leaks In Porous Medical Packaging By Dye Penetration.

ASTM F1140/F1140M-13, Standard Test Methods For Internal Pressurization Failure Resistance Of Unrestrained Packages.
ISO 11737-1 Third Edition 2018-01 Sterilization of health care products-Microbiological methods-Part 1: Determination of a population of microoranisms on product.
ASTM F1886/F1886M–16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection.
ASTM F1980–16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
ISO 10993-5 Third Edition 2009-06-01 Biological evaluation of medical devices- part 5 tests for In Vitro Cytotoxicity.
ISO 10993-7 Second Edition 2008-10-15 Biological evaluation of medical devices-Part 7 Ethylene oxide sterilization residuals [Including: Technical corrigendum 1(2009)].
ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization.
USP 37 NF 32:2014 <71> Sterility Tests
USP 37-NF 32:2014 <85> Bacterial endotoxins test
ISO 11135 Second Edition 2014 -07-15 Sterilization of health care products — Ethylene oxide — Requirements for development, validation and routine control of a sterilization process for medical devices

9. Substantially Equivalent Conclusion

Based on the technological characteristics and overall performance of the devices in the bench testing, there are no significant differences exist between the proposed devices and the predicate devices, the proposed devices do not raise any new issues of safety and effectiveness, and the performances as well as the predicate device. It is determine that the proposed devices and the predicate devices are substantially equivalent.