May 27, 2022

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

Re: K212669
Trade/Device Name: Single Use Hemoclip
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: Class II
Product Code: PKL
Dated: April 21, 2022
Received: April 28, 2022

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,

for
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)*
K212669

Device Name
Single Use Hemoclip

Indications for Use *(Describe)*
The Single Use Hemoclip Device is indicated for endoscopic clip placement within the gastrointestinal tract for the purpose of:
(1) endoscopic marking,
(2) hemostasis for
(a) mucosal / sub-mucosal defects < 3cm,
(b) bleeding ulcers,
(c) polyps < 1.5cm in diameter,
(d) diverticula in the colon,
(3) as a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively
(4)the age of the intended population for the device is for patients who are 18 and older.

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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Section 5 510(k) Summary(21CFR 807.92)

1. Submitter's information

Name: Zhejiang Chuangxiang Medical Technology Co., LTD.

Address: Room 101,201,301,401,501, Building 50, No.650 Hongfeng Road Donghu Street, Yuhang District, Hangzhou City, Zhejiang Province， 311100， P.R. China

Contact person: Lucius.Long
Telephone: 86-571-89167088-8680
Fax: 86-571-89167086

2. Date of Submission

09-Aug- 2021

3. Device

Name of the device: Single Use Hemoclip
Classification name: Hemorrhoidal ligator
Regulation class: 2
Regulation number:876.4400
Panel: Gastroenterology/Urology
Product code: PKL

4. Predicate device

510(k) Number: K172762,
Product Name: Single Use Hemoclip

510(k) Number: K202333
Product Name: Lockado™ Repositionable Hemostasis Clip

5. Device description

The proposed device Single Use Hemoclip is a sterile, single-use endoscopic clipping device, intended to be used for endoscopic marking, hemostasis for mucosal/submucosal defects in digestive tract. It consists of two main components, delivery system and clip assembly. And it is offered in different dimensions.

6.Indication for use

The Single Use Hemoclip is indicated for endoscopic clip placement within the gastrointestinal tract for the purpose of:
(1) endoscopic marking,
(2) hemostasis for
(a) mucosal / sub-mucosal defects < 3cm,
(b) bleeding ulcers,
(c) polyps < 1.5cm in diameter,
(d) diverticula in the colon,
(3) as a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively
(4) the age of the intended population for the device is for patients who are 18 and older.

6. Summary of comparison of technological characteristics with the predicate device

The Single Use Hemoclip incorporates substantially equivalent device materials, design, configuration, packaging fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the Zhejiang Chuangxiang Medical Technology Co., LTD. (K172762) and Micro-Tech predicate devices (K202333).

Comparison to Predicate Devices:

Item	Proposed device	Predicate device	Additional predicate device	Comparison to Predicate Devices
Device name	Single use hemoclip	Single use hemoclip	Lockado™ Repositionable Hemostasis Clip	Similiar
510(k) number	/	K172762	K202333	Different 510(k) number
Manufacturer	Zhejiang Chuangxiang medical technology Co., LTD.	Zhejiang Chuangxiang medical technology Co., LTD.	Micro-Tech(Nanjing) Co., Ltd.	Same
Product Code	PKL	PKL	PKL	Same
Regulation No.	876.4400	876.4400	876.4400	Same
Class	2	2	2	Same
Supplied Sterile	Yes	Yes	Yes	Same
Configuration	Delivery system and clip assembly	Delivery system and clip assembly	Delivery system and clip assembly	Same
Clip opening	9mm, 12mm,13mm,15mm,16mm	9mm, 12mm,13mm,15mm	8mm, 11mm and 16mm	Similar
Minimal working channel	2.8mm	2.8mm	2.8mm	Same
Working Length	1650mm, 1950mm, 2300mm, 2700mm	1650mm, 1950mm, 2300mm, 2700mm	1650mm, 1950mm, 2350mm, 2700mm	Same
Indications for	The single use hemoclip is	The single use hemoclip is	The Lockado™ Repositionable	Same

Use	indicated for endoscopic clip placement within the gastrointestinal tract for the purpose of: (1) endoscopic marking, (2) hemostasis for (a) mucosal / sub-mucosal defects < 3cm, (b) bleeding ulcers, (c) polyps < 1.5cm in diameter, (d) diverticula in the colon, (3) as a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively (4)the age of the intended population for the device is for patients who are 18 and older.	indicated for endoscopic clip placement within the gastrointestinal tract for the purpose of: (1) endoscopic marking, (2) hemostasis for (a) mucosal / sub-mucosal defects < 3cm, (b) bleeding ulcers, (c) polyps < 1.5cm in diameter, (d) diverticula in the colon, (3) as a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively (4)the age of the intended population for the device is for patients who are 18 and older.	Hemostasis Clip is indicated for Endoscopic clip placement within the Gastrointestinal tract in adult patients only via a straight or side viewing flexible endoscope for the purpose of : (1) Endoscopic marking; (2) Hemostasis for (a) mucosal / sub-mucosal defects <3cm, (b) bleeding ulcers, (c) polyps < 1.5cm in diameter, (d) diverticula in the colon, (e) Arteries < 2 mm, (f) Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection; (3) As a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively. (4) Anchoring to affix jejunal feeding (2) tubes to the wall of the small bowel.	
Repositionability	Clip reopened and	Clip reopened and	Clip reopened and repositioned up to 5	Same

	repositioned up to 8 times	repositioned up to 8 times	times	
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	Three years	Three years	Same
MRI information	Comply with ASTM F 2503, ASTMF 2052, ASTM F2119, ASTM F2182, ASTM F2213	/	Comply with ASTM F 2503, ASTMF 2052, ASTM F2119, ASTM F2182, ASTM F2213	Same

7. Performance data

The proposed device the Single Use Hemoclip meets the requirements of ISO 10993 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing", ISO 11135-1 "Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization Processes for Medical Devices", and ISO 10993-7 "Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals",

The following bench tests were performed on the Single Use Hemoclip:

Dimensional verification	Mechanical Integrity of Clip Assembly
Clamping Strength Testing	Tensile Strength Testing
Release Force Testing	Rotation Testing

The testing performed demonstrated that the proposed and predicate delivery systems are equivalent.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusions

Based on the indications for use, technological characteristics, and safety and performance testing, Single Use Hemoclip has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared the Single Use Hemoclip (K172762) and Lockado^{TM} Repositionable Hemostasis Clip (K202333).