March 7, 2018

Zhejiang Chuangxiang Medical Technology Co., LTD.
Lucius Long
Quality Supervisor
301B, No.22, XinYan Road
Hangzhou, Zhejiang 311100
China

Re: K172758
Trade/Device Name: Rotatable Snares, Non-Rotatable Snares
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: FDI
Dated: January 4, 2018
Received: January 4, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172758

Device Name
Rotatable Snares
Non-Rotatable Snares

Indications for Use *(Describe)*
The Polypectomy Snare is used endoscopically in the removal and/or and cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the gastrointestinal 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

Trade Name: Rotatable Snares, Non-Rotatable Snares
Common Name: Polypectomy Snare
Classification name: Endoscopic electrosurgical unit and accessories
Regulation class: 2
Regulation number:876.4300
Panel: Gastroenterology/Urology
Product code: FDI

3. Predicative device

510(k) Number: K160637,
Product Name: Rotatable Snares

4. Device description

The Polypectomy Snare consists of a flexible wire cable (core wire) and loop which can be extended and retracted from the Snare's flexible outer sheath using a three-ring handle. The flexible cable and loop can also be rotated 360° using the rotation actuator on the handle. The inner diameter of the sheath is PTFE to provide minimal friction during extension, rotation, and retraction of the loop from the sheath. When passed through an endoscope and activated, the Snare delivers a monopolar electrical current to cut and cauterize tissue with the loop.
For All models information in this submission, please refer to below table 1.

Zhejiang Chuangxiang Medical Technology Co.,Ltd

Table 1 List of models in this submission

Model		Part Number	Max. OD (mm)	Snare Loop Opening Width (mm)	Effective Length (mm)
			≤ D（mm）	B $^{+10\%}_{-20\%}$	L（mm）±100
Standard (C)	E Oval	MD-E-SNC181024	Φ1.8	10	2400
		MD-E-SNC181524	Φ1.8	15	2400
		MD-E-SNC181018	Φ1.8	10	1800
		MD-E-SNC181518	Φ1.8	15	1800
		MD-E-SNC241024	Φ2.4	10	2400
		MD-E-SNC241524	Φ2.4	15	2400
		MD-E-SNC241018	Φ2.4	10	1800
		MD-E-SNC241518	Φ2.4	15	1800
		MD-E-SNC242516	Φ2.4	25	1600
		MD-E-SNC242524	Φ2.4	25	2400
		MD-E-SNC243224	Φ2.4	32	2400
		MD-E-SNC242518	Φ2.4	25	1800
		MD-E-SNC243218	Φ2.4	32	1800
	H Hexagonal	MD-H-SNC241024	Φ2.4	10	2400
		MD-H-SNC241524	Φ2.4	15	2400
		MD-H-SNC242224	Φ2.4	22	2400
		MD-H-SNC243224	Φ2.4	32	2400
		MD-H-SNC241018	Φ2.4	10	1800
		MD-H-SNC241518	Φ2.4	15	1800
		MD-H-SNC242218	Φ2.4	22	1800
		MD-H-SNC243218	Φ2.4	32	1800
	C Crescent	MD-C-SNC241524	Φ2.4	15	2400
		MD-C-SNC242524	Φ2.4	25	2400
		MD-C-SNC243224	Φ2.4	32	2400
		MD-C-SNC241518	Φ2.4	15	1800
		MD-C-SNC242518	Φ2.4	25	1800
		MD-C-SNC243218	Φ2.4	32	1800

Zhejiang Chuangxiang Medical Technology Co.,Ltd

	R Round	MD-R-SNC243224	Φ2.4	32	2400
		MD-R-SNC243218	Φ2.4	32	1800
Rotational (R)	E Oval	MD-E-SNR181024	Φ1.8	10	2400
		MD-E-SNR181524	Φ1.8	15	2400
		MD-E-SNR181018	Φ1.8	10	1800
		MD-E-SNR181518	Φ1.8	15	1800
		MD-E-SNR241024	Φ2.4	10	2400
		MD-E-SNR241524	Φ2.4	15	2400
		MD-E-SNR241018	Φ2.4	10	1800
		MD-E-SNR241518	Φ2.4	15	1800
		MD-E-SNR242516	Φ2.4	25	1600
		MD-E-SNR242524	Φ2.4	25	2400
		MD-E-SNR243224	Φ2.4	32	2400
		MD-E-SNR242518	Φ2.4	25	1800
		MD-E-SNR243218	Φ2.4	32	1800
	H Hexagonal	MD-H-SNR241024	Φ2.4	10	2400
		MD-H-SNR241524	Φ2.4	15	2400
		MD-H-SNR242224	Φ2.4	22	2400
		MD-H-SNR243224	Φ2.4	32	2400
		MD-H-SNR241018	Φ2.4	10	1800
		MD-H-SNR241518	Φ2.4	15	1800
		MD-H-SNR242218	Φ2.4	22	1800
		MD-H-SNR243218	Φ2.4	32	1800
	C Crescent	MD-C-SNR241524	Φ2.4	15	2400
		MD-C-SNR242524	Φ2.4	25	2400
		MD-C-SNR243224	Φ2.4	32	2400
		MD-C-SNR241518	Φ2.4	15	1800
		MD-C-SNR242518	Φ2.4	25	1800
		MD-C-SNR243218	Φ2.4	32	1800
	R Round	MD-R-SNR243224	Φ2.4	32	2400
		MD-R-SNR243218	Φ2.4	32	1800

Zhejiang Chuangxiang Medical Technology Co.,Ltd

5. Indication for use

The Polypectomy Snare is used endoscopically in the removal and/or and cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the gastrointestinal tract.

6. Technological Characteristics

The Polypectomy Snare incorporates substantially equivalent device materials, design, configuration, packaging fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the Boston Scientific Corporation predicate devices.

Comparison to predicate Devices:

Item	Proposed device	Predicate device	Comparison to Predicate Devices
Device name	Polypectomy Snare	Rotatable Snares	Similiar
510(k) number	NA, new submission	K160637	Different 510(k) number
Manufacturer	Zhejiang Chuangxiang medical technology Co., Ltd.	Boston Scientific Corporation	Different manufacturer
Product Code	FDI	FDI, FGX	Same
Regulation No.	876.4300	876.4300	Same
Class	2	2	Same
Supplied Sterile	Yes	Yes	Same
Configuration	Oval, Hexagonal, Crescent, Round	Oval, Hexagonal, Crescent, Round	Same
Minimal working channel	2.8mm	2.8mm	Same
Sheath OD	2.4mm	2.4mm	Same
Working Length	1600mm,1800mm,2400mm	2400mm	similar
Loop width	10mm,15mm,22	10mm,11mm,13mm,15	similar

Zhejiang Chuangxiang Medical Technology Co.,Ltd

	mm,25mm,32mm,	mm,20mm,25mm,27mm,30 mm,33mm	
Indications for Use	The Polypectomy Snare is used endoscopically in the removal and/or and cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the gastrointestinal tract.	The Rotatable Snare is used endoscopically in the removal and/or and cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the gastrointestinal tract.	Same
Single Use	Yes	Yes	Same
Packaging	Single-use EO sterilized pouch with one device per pouch	Single-use EO sterilized pouch with one device per pouch	Same

7. Performance data

In-vitro Testing has been performed and all components, subassemblies, and/or full devices met the required specifications for the completed tests. A summary of the test results has been provided for Working Length, Tortuous Path Functionality, Rotation Capability, Handle to Core Wire Tensile Strength, Electrical Resistance, Electrical Safety and Snare Actuation.

The EO residual and ECH residual were 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 26, 2016. The cytotoxicity, sensitization, intracutaneous irritation, system toxicity pyrogen and endotoxin tests were performed to demonstrate the biocompatibility of the device.

Tests on Electromagnetic Compatibility and Electrical Safety were performed in accordance to requirements per AAMI/ANSI ES 60601-1:2005/(R)2012 and AAMI/ANSI/IEC 60601-2-2:2009.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusions

Chuangxiang medical has demonstrated that the proposed Polypectomy Snare are substantially equivalent to Boston Scientific Corporation's currently marketed Rotatable Snares(K160637).