June 14, 2018

Leo Medical Co., Ltd.
Yunpeng Ma
Quality and Registration Director
2 Floor, 10 Building
18 Huashan Road
Changzhou City, 213022 Jiangsu Province
CHINA

Re: K172985
Trade/Device Name: Ligation Device
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: Class II
Product Code: FHN, MND
Dated: May 16, 2018
Received: May 18, 2018

Dear Yunpeng Ma:

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 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,

Glenn B. Bell -S

for 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)*

K172985

Device Name
Ligation Device

Indications for Use *(Describe)*
The device is designed to be used with an Endoscope to deliver a Ligation Loop designed to prevent or control bleeding following polypectomy of pedunculated polyps.

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:

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*"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."*

# Tab #2 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K172985

1. Date of Preparation: 04/28/2018

2. Sponsor Identification

**Leo Medical Co., Ltd.**
2 Floor, 10 Building, 18 Huashan Road, Changzhou City, 213022, Jiangsu Province, China

Establishment Registration Number: Not yet registered.

Contact Person: Yunpeng MA
Position: Quality and Registration Director
Tel: +86-519-85150750-620
Fax: +86-519-85150790
Email: ypma@leomed.cn

3. Identification of Proposed Device

Trade Name: Ligation Device
Common Name: Ligator Device

Regulatory Information

Regulation Name: Hemorrhoidal ligator
Classification: 2
Product Code: FHN
Subsequent Product Code: MND
Regulation Number: 876.4400
Review Panel: Gastroenterology/ Urology

Intended Use Statement:

The device is designed to be used with an Endoscope to deliver a Ligation Loop designed to prevent or control bleeding following polypectomy of pedunculated polyps.

Device Description

The Ligation Device is sterile and single-use, which consists of two main components, ligation loop and delivery system. And these two components provided in different sizes to consist different specifications of ligation device.

4. Identification of Predicate Device

510(k) Number: K964661
Product Name: Olympus HX-20-1 Endoscopic Ligator

5. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials.
- ISO 10993-1:2009+AC2010 Biological evaluation of medical device- Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]
- ISO 10993-5:2009, Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity.
- ISO 10993-6:2016 Biological Evaluation Of Medical Devices -- Part 6: Tests For Local Effects After Implantation
- ISO 10993-7:2008+AC:2009, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals.
- ISO 10993-10:2010, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.
- ISO 10993-11: 2006, Biological Evaluation Of Medical Devices - Part 11: Tests For Systemic Toxicity
- ISO 11135:2014 Sterilization of health-care products-Ethylene Oxide- requirements for the development, validation and routine control of a sterilization process for medical devices

6. Clinical Test Conclusion

No clinical study is included in this submission.

7. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

| Item | | Proposed Device | Predicate Device K964661 |
|---|---|---|---|
| Product Code | | MND and FHN | MND and FHN |
| Regulation Number | | 876.4400 | 876.4400 |
| Class | | 2 | 2 |
| Intended Use | | The ligation device is intended to prevent or control bleeding following polypectomy of pedunculated polyps. | The Olympus HX-20-1 Endoscopic Ligator has been designed to be used with Olympus endoscopes in delivering a MAJ-254 Standard Ligation Loop or MAJ-340 Small ligation Loop, designed to prevent or control bleeding following polypectomy of pedunculated polyps. |
| Single Use | | Yes | Not |
| Configuration | | Ligation loop | Loop |
| | | Delivery system | FG Handle |
| | | | Coil sheath |
| Open width | | 15, 20, 30, 40mm | 13~30mm |
| Minimal working channel | | 2.8mm | 2.8mm |
| Working length | | 1650, 1950, 2300mm | 1650~2300mm |
| Performance | | Release force, tensile strength, clamping strength | Release force, tensile strength, clamping strength |
| Biocompatibility | Cytotoxicity | No cytotoxicity | Comply with ISO 10993 requirements |
| | Sensitization | No sensitization | |
| | Irritation | No irritation | |
| | Acute Systemic Toxicity | No acute systemic toxicity | |
| | Subchronic Systemic Toxicity | No subchronic systemic toxicity | |
| | Subcutaneous Implantation | The histological responses around the test sample were similar to the control sample. | |
| | Pyrogenicity | No pyrogenicity | |
| Sterilization | | EO sterilized, SAL $10^{-6}$ | Moist heat, SAL $10^{-6}$ |
| Shelf life | | Two years | No requirement |
| Labeling | | Conform to 21 CFR part 801 | Conform to 21 CFR part 801 |

The proposed device and predicate device share similar intended use and performance. The proposed device is single-use, which is sterilized by the manufacturer, and the sterilization cycle has been validated per ISO 11135. The coil sheath and FG handle of predicate device is reusable, and sterilized by user. Because of the re-sterilization, the safety and performance of the predicate devices would be influenced and reduced, and this condition would not be occur to the proposed device, therefore, the difference will not affect substantially equivalency.

8. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.