March 5, 2019

Micro-Tech (Nanjing) Co., Ltd.
Becky Li
Quality and Regulatory Affairs Director
NO. 10 Gaoke Third Road
Nanjing, Jiangsu 210032
China

Re: K190030
Trade/Device Name: Embrella™ Endoscopic Distal Attachment
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FED
Dated: December 27, 2018
Received: January 7, 2019

Dear Becky Li:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Mark J. Antonino -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)*

K190030

Device Name

Embrella™ Endoscopic Distal Attachment

Indications for Use *(Describe)*

Embrella™ Endoscopic Distal Attachment is intended to be attached to the distal end of the endoscope to facilitate endoscopic therapy and maintain an appropriate endoscopic field of view.

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."

Tab 7

510K Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K190030

1. **Date of Preparation: 2019-03-01**

2. **Sponsor Identification**

Micro-Tech (Nanjing) Co., Ltd.

No.10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing, Jiangsu Province, PRC

Establishment Registration Number: 3004837686

Contact Person: Becky Li

Position: Quality and Regulatory Affairs Director

Tel: +86-25-58646378

Fax: +86-25-58744269

Email: Beckyli_mt@outlook.com

3. **Identification of Proposed Device**

Trade Name: Embrella™ Endoscopic Distal Attachment

Common Name: Endoscopic Distal Attachment

Regulatory Information

Classification Name: Endoscope and accessories

Classification: 2

Product Code: FED

Regulation Number: 21 CFR 876.1500

Review Panel: Gastroenterology/Urology

4. Identification of Predicate Device

510(k) Number: K133359

Product Name: Endoring™

Manufacturer: EndoAid, Ltd.

5. Indications for Use

Embrella™ Endoscopic Distal Attachment is intended to be attached to the distal end of the endoscope to facilitate endoscopic therapy and maintain an appropriate endoscopic field of view.

6. Device Description

The proposed device Embrella™ Endoscopic Distal Attachment is an additional device, made of medical grade silicone rubber designed to attach to the distal end of the endoscope. Its shape is umbrella shaped, with six flexible wings that easily to fold backwards and forwards. It can be used to facilitate endoscopic therapy and maintain an appropriate endoscopic field of view.

Embrella™ Endoscopic Distal Attachment has two models, one is EM-S-01, which is compatible with endoscopy distal diameter 12.8-14.5mm; the other is EM-S-02, which is compatible with endoscopy distal diameter 11.5-13.0mm.

7. Comparison of Technological Characteristics

The **Embrella™ Endoscopic Distal Attachment** incorporates substantially equivalent device materials, design, configuration, packaging fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate device Endoring™.

Comparison to predicate Devices:

MICRO-TECH (Nanjing) Co., Ltd.
南京微创医学科技股份有限公司

510k summary

Item	Proposed Device **Embrella™ Endoscopic Distal Attachment**	Predicate Device **Endoring™ (K133359)**	Substantial Equivalence
Product Code	FED	FED	Same
Regulation No.	21 CFR 876.1500	21 CFR 876.1500	Same
Class	2	2	Same
Supplied in Sterile	Yes	Yes	Same
Material	Silicone Rubber	Silicone Rubber	Same
Configuration	One short tube with 6 flexible wings	One short tube with 6 flexible wings	Same
Compatible endoscopy working channel	11.5-13.0mm 12.8-14.5mm	11.5-13.0mm 12.8-14.5mm	Same
Indications for Use	Embrella™ Endoscopic Distal Attachment is intended to be attached to the distal end of the endoscope to facilitate endoscopic therapy and maintain an appropriate endoscopic field of view.	The EndoRings is intended to be attached to the distal end of the endoscope to facilitate endoscopic therapy, to be used for the following: *Keeping the suitable depth of endloscope's view field	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
Shelf Life	One years	Three years	Different

8. Performance Data

The proposed device the **Embrella™ Endoscopic Distal Attachment** meets the requirements of ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within A Risk Management Process”, ISO 11135 “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 **Embrella™ Endoscopic Distal Attachment**

- Dimension;
- Operating Performance
- Matching Performance;
- Tension Performance;

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

9. Animal Testing

Endoscopy View Testing were performed on the Embrella™ Endoscopic Distal Attachment.

The testing performed demonstrated that the proposed device and predicate device are equivalent,

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Substantially Equivalent (SE) Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the **Embrella™ Endoscopic Distal Attachment** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared predicate device **EndoRing™ (K133359).**