December 23, 2020

Hangzhou AGS MedTech Co., Ltd.
Yanping Fu
RA Supervisor
Building 5, Building 6, No.597 Kangxin Road Yuhang District
Hangzhou, Zhejiang 311106
China

Re: K202237
Trade/Device Name: Locking device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: ODC
Dated: November 17, 2020
Received: December 21, 2020

Dear Yanping Fu:

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.
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)*
K202237

Device Name
Locking Device

Indications for Use *(Describe)*
This device is an accessory to be used with endoscopic biliary devices to lock the guidewire(s) in place during ERCP procedure. The device is supplied sterile and intended for single use only.

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.***

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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."*

# 510(k) Summary

We submit this 510(k) Summary as per 21 CFR 807.92, it meets the content and format regulatory requirements.

**5.1 Submitter**

| | |
|---|---|
| Submitted by/Owner: | Hangzhou AGS MedTech Co., Ltd.<br>Building 5, Building 6, NO.597 Kangxin Road Yuhang District, Hangzhou, Zhejiang 311106 China |
| Establishment Registration Number: | 3010288205 |
| Registration Status: | Active |
| Contact Person: | Yanping Fu<br>Phone: 0086-15958493282<br>Fax: 0086- 0571-87671225<br>Email: fuyp@bioags.com |
| Date Prepared: | July 30, 2019 |

**5.2 Proposed Device**

| | |
|---|---|
| Trade Name: | Locking device |
| Device Name: | Locking device |
| Common Name: | Locking device |
| Regulation class: | Class II |
| Regulation Number: | 876.1500 |
| Regulation Description: | Endoscope and accessories. |
| Review Panel: | Gastroenterology/Urology |
| Product Code: | ODC |
| Product Code Name: | Endoscope Channel Accessory |

**5.3 Predicate Device**

| | |
|---|---|
| Trade Name: | Wilson-Cook USW Cap and Wire Lock |
| Device Name: | Wilson-Cook USW Cap and Wire Lock |
| Common Name: | Cap and Wire Lock |
| 510(k) Number: | K040137 |
| Regulation class: | Class II |
| Regulation Number: | 876.1500 |
| Regulation Description: | Endoscope and accessories. |
| Review Panel: | Gastroenterology/Urology |
| Product Code: | OCY |
| Product Code Name: | Endoscopic Guidewire, Gastroenterology-Urology |

## 5.4 Device Description

The proposed Locking Device is one-piece integrated system that secures onto the accessary channel of an endoscope. The access port in the center of the cap allows access of wire guides and other biliary accessories. The wire guide lock allows the practitioner to lock the wire guide in place for continued ductal access while proceeding with other ERCP therapies. This device consists of locking device and biopsy cap.

## 5.5 Indication for use statement

This device is an accessory to be used with endoscopic biliary devices to lock the guidewire(s) in place during ERCP procedure. The device is supplied sterile and intended for single use only.

## 5.6 Comparison of Technology Characteristics

Our proposed device Locking Device is substantially equivalent to the predicate devices. The differences between the Locking Device and the predicate devices do not raise any questions regarding its safety and effectiveness. The differences are listed in the table below.

| Item | | Proposed device | Predicate device | Comparison |
|---|---|---|---|---|
| Recommended Wire Guide Diameter inch | | 0.025inch<br>0.035inch<br>0.038inch | Unknown | Different.<br>We have conducted guide wire fixing force performance for our proposed device, demonstrate that our Locking device is suitable for guide wire with 0.025inch/0.035inch/0.038inch diameter. For details, please refer to Appendix 18-1 Bench performance Testing report. |
| Biological | Materials or substances in contact with the same human tissue or body fluids | ABS, Silica gel | Unknown | Different.<br>Biocompatibility tests have been done for the difference. Biological risks are acceptable. |
| | Biocompatibility | In Vitro Cytotoxicity Test: ISO 10993-5: 2009;<br>Skin sensitization Test: ISO 10993-10: 2010;<br>Intracutaneous Reactivity Test: ISO | Unknown | |

| Item | | Proposed device | Predicate device | Comparison |
|---|---|---|---|---|
| | | 10993-10: 2010; | | |

### 5.7 Applicable Guidance Document
NA

### 5.8 Performance Data
The Locking Device meets all design specifications and medical device standards for biocompatibility (ISO 10993) and sterility (ISO 11135). The non-clinical performance meets the design specification and shows substantial equivalence to the predicated device.

### 5.9 Clinical Test
No Clinical test is included in this submission.

### 5.10 Conclusion
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, Based on the information provided in this premarket notification, Hangzhou AGS MedTech Co., Ltd has demonstrated that proposed device Locking Device is substantially equivalent to the predicate devices.