December 16, 2020

Hangzhou AGS MedTech Co., Ltd.
Chunqi Han
R&D Director
Building 5, Building 6, No.597 Kangxin Road Yuhang District
Hangzhou, Zhejiang 311106
China

Re: K201509
Trade/Device Name: Disposable Stone Extraction basket
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: Class II
Product Code: LQR
Dated: November 18, 2020
Received: November 20, 2020

Dear Chunqi Han:

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,

Glenn B. Bell, Ph.D.
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)*
K201509

Device Name
Disposable Stone Extraction Basket

Indications for Use *(Describe)*
The device is used for the endoscopic removal of biliary stones and foreign bodies.

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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# K201509
# 510(k) Summary

# 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 18, 2019 |

**5.2 Proposed Device**

| | |
|---|---|
| Trade Name: | / |
| Device Name: | Disposable Stone Extraction Basket |
| Common Name: | Disposable Stone Extraction Basket |
| Regulation class: | Class II |
| Regulation Number: | 876.5010 |
| Regulation Description: | Biliary Catheter and Accessories |
| Review Panel: | Gastroenterology/Urology |
| Product Code: | LQR |
| Product Code Name: | Dislodger, Stone, Biliary |

**5.3 Predicate Device**

| | |
|---|---|
| Trade Name: | MEMORY BASKET 5F SOFT WIRE |
| Device Name: | MEMORY BASKET 5F SOFT WIRE |
| Common Name: | Non-Lithotripsy Extraction Basket |
| 510(k) Number: | K171969 |
| Regulation class: | Class II |
| Regulation Number: | 876.5010 |
| Regulation Description: | Biliary Catheter and Accessories |
| Review Panel: | Gastroenterology/Urology |
| Product Code: | LQR |
| Product Code Name: | Dislodger, Stone, Biliary |

**5.4 Device Description**

The subject Disposable Stone Extraction Basket is comprised of a stainless steel/nitinol

basket at the distal end of a sheath with handle. Basket is advanced out of and retracted into the single lumen polytetrafluoroethylene catheter sheath using the handle component's actuator. The device is not compatible with any mechanical lithotripter. EO Sterilization and use for single use only.

**5.5 Indication for use statement**

The device is used for the endoscopic removal of biliary stones and foreign bodies.

**5.6 Comparison of Technology Characteristics**

Our proposed device Disposable Stone Extraction Basket is substantially equivalent to the predicate devices. The differences between the Disposable Stone Extraction Basket 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 |
|---|---|---|---|---|
| Common name | | Disposable Stone Extraction Basket | Non-Lithotripsy Extraction Basket | / |
| Trade name | | / | MEMORY BASKET 5F SOFT WIRE | / |
| Model number | | 5061 series, 5062 series, 50631series, 5064 series, 5065 series, 50610 series, 50611 series, 50613 series, 50614 series. | MSB5-2X4 | / |
| 510(k) submitter | | Hangzhou AGS MedTech Co., Ltd. | Wilson-Cook Medical, Inc. | / |
| 510(k) number | | / | K171969 | / |
| Technical | Sheath Max outer diameter | 5061/5062/50610/50611:1.8/2.4/3.2mm;<br>5063:2.4mm;<br>5064/5065/50613/50614:1.8mm; | 5Fr（≈1.67mm） | Similar.<br>For different size of endoscope channel, we design different sheath max. outer diameter, operator can choose different sheath max. outer diameter according to different clinical use situation. The difference does not raise different questions regarding its safety and effectiveness. |
| | Minimum Accessory Channel | 2.0mm/2.8mm/3.7mm | 2mm | Similar.<br>Difference size of sheath max outer diameter suit for different endoscope channel. The difference does not raise different questions regarding its safety and effectiveness. |
| | Open width | 10,15,20,25,30mm | 20mm | Similar.<br>We design different open width of basket for different size stone or foreign bodies. The difference does not |

| Item | | Proposed device | Predicate device | Comparison |
|---|---|---|---|---|
| | | | | raise different questions regarding its safety and effectiveness. |
| | Working length | 5061/2/3/10/11: 1950mm;<br>5064/5/13/14:700mm; | 2000mm | Similar. |
| | Handle type | Two handle type:<br>One handle type: | Rotatable pin vise, two handle type. | Similar.<br>We design one handle type for simple operation. The difference does not raise different questions regarding its safety and effectiveness. |
| | Performance | Tensile strength;<br>Operation smoothly;<br>Rotate smoothly (for rotatable models) ; | Tensile Testing;<br>Flexibility Testing;<br>Rotate smoothly; | Different.<br>We conduct bench performance for our proposed device and the predicate device, please refer to Section 18 of this submission, the test results show that our proposed device is substantial equivalence with the predicate device. |
| Biological | Materials or substances in contact with the same human tissue or body fluids | 5063: SUS 303, SUS 304, PTFE;<br>5061-5062, 5064-5065, 50610, 50611, 50613, 50614: SUS 303, Nitinol, PTFE; | Basket: metal wire;<br>Catheter sheath: polytetrafluoroethylene (PTFE); | Different.<br>Biocompatibility tests have been done for the difference. Biological risks are acceptable, please refer to Section 15 of this submission. |

| Item | | Proposed device | Predicate device | Comparison |
|---|---|---|---|---|
| | Biocompatibility | In Vitro Cytotoxicity Test<br>ISO 10993.5-2009;<br>Skin sensitization Test,<br>Intracutaneous Reactivity Test<br>ISO 10993.10-2010; | Unknown | |

### 5.7 Applicable Guidance Document

NA

### 5.8 Performance Data

The Disposable Stone Extraction Basket 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 Disposable Stone Extraction Basket is substantially equivalent to the predicate devices.