April 27, 2021

Anrei Medical (Hangzhou) Co., Ltd.
Huibing Yang
Director, Regulatory Affairs
No.3 Ave.8, HEDA
Hangzhou, Zhejiang 310018
CHINA

Re: K210660
Trade/Device Name: Stone Retrieval Balloon Catheter
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: GCA
Dated: March 1, 2021
Received: March 4, 2021

Dear Huibing Yang:

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,

Je Hi An, Ph.D.
Acting 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)*
K210660

Device Name
Stone Retrieval Balloon Catheter

Indications for Use *(Describe)*
The device is intended for endoscopic removal of biliary stones. 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.

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510(k) Summary

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

1. **Date of Preparation:** 04/27/2021

2. **Sponsor Identification**

Anrei Medical (Hangzhou) Co., Ltd.
No. 3, Ave 8, Hangzhou Economic Development Area, 310018 Hangzhou, P.R.China

Establishment Registration Number: 3006621103
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Email: **huibing.yang@anrei.com.cn**

3. **Identification of Proposed Device**

Trade Name: Stone Retrieval Balloon Catheter
Common Name: Balloon Catheter

Regulatory Information
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulation Class: II
Product Code: GCA
Device Panel: Gastroenterology/Urology

Indications for Use Statement:
The device is intended for endoscopic removal of biliary stones. The device is supplied sterile and intended for single use only.

Device Description:
The Stone Retrieval Balloon Catheter is comprised of a latex balloon mounted at the distal end of a Pebax catheter with three internal lumens. For some specifications, the balloon can be inflated to 8.5mm, 12mm, 15mm and 18mm only. But for some specifications, the balloon can be inflated to three sizes, 8.5mm, 12mm and 15mm diameters, or 12mm, 15mm and 18mm. Radiopaque bands placed at the distal and proximal ends of the balloon provide fluoroscopic visualization of the balloon location. The catheter length is 2000mm with an outer diameter of 2.3mm. The three lumens correspond to a balloon inflation port, a wire guide port and an injection port. A stopcock is included at the proximal end of the balloon inflation port to control air movement into or out of the balloon. For rapid exchange models, there is a small hole on the catheter which is about

200mm far away from the distal end. It is used to insert the guide wire rapidly. EO sterilization and use for single use only.

4. Identification of Predicate Device(s)

510(k) Number: K200173
Product Name: Stone Retrieval Balloon
Manufacturer: Hangzhou AGS MedTech Co., Ltd.

5. Comparison of Technological Characteristics

Item	Proposed Device	Predicate Device K200173	Remark
Device name	Stone Retrieval Balloon Catheter	Stone Retrieval Balloon	/
Classification name	Biliary catheter and accessories	Biliary catheter and accessories	Same
Classification	II	II	Same
Product code	GCA	GCA	Same
Regulation number	21 CFR 876.5010	21 CFR 876.5010	Same
Intended Use/ Indications for Use	The device is intended for endoscopic removal of biliary stones. The device is supplied sterile and intended for single use only.	The device is intended for endoscopic removal of biliary stones. The device is supplied sterile and intended for single use only.	Same
Catheter O.D.	2.3mm	2.4mm	Analysis 1
Catheter Length	2000mm	2000mm	Same
Balloon Inflated O.D.	8.5/12/15/18/8.5-12-15/12-15-18	8.5/12/15/18/8.5-12-15/13-15-18	Analysis 2
Recommended Guidewire	0.035/0.025in	0.035/0.025in	Same
Single Use	Yes	Yes	Same
Supplied Sterile	Yes	Yes	Same
Sterilization Method	Ethylene oxide (EO)	Ethylene oxide (EO)	Same
Shelf Life	Two years	Two years	Same
Labeling	Comply with 21 CFR Part 801	Comply with 21 CFR Part 801	Same
Packaging	Paper and film with one device per package	Paper and film with one device per package	Same
Patient contact material	Three internal lumens: Pebax; Radiopaque band: Ta; Bind wire: PET; Balloon: Natural latex; Binder: UV-curing adhensive; Marker: TPU ink.	Sheath: Pebax; Radiopaque band: Tal; Bind wire: PET; Laxtex balloon: Natural latex; Binder: UV-curing adhensive; Marker: Polyurethane ink.	Analysis 3
Biocompatibility	In Vitro Cytotoxicity Test : ISO	In Vitro Cytotoxicity Test : ISO	Same

	10993-5: 2009; Skin sensitization Test :ISO 10993-10: 2010; Intracutaneous Reactivity Test: ISO 10993-10: 2010.	10993-5: 2009; Skin sensitization Test :ISO 10993-10: 2010; Intracutaneous Reactivity Test: ISO 10993-10: 2010.	
Analysis 1: Slightly smaller. The slight difference does not affect the compatibility with the endoscope of the minimum working channel size of 2.8mm. Please refer to bench test. Analysis 2: There is a literature that retrieval balloon catheter is used to remove stones in the bile duct which the mean common bile duct (CBD) dilation was 19.2mm±3.9 and the mean size of stones 15.8±2.9. The tolerance of balloon inflation O.D. is (+2, -1) mm, and the slight difference does not affect the device performance. Please refer to bench test. Analysis 3: Biocompatibility test has been conducted on the proposed device and the test result can meet the requirements of ISO 10993 series standard. Therefore, this difference will not affect substantial equivalence between proposed device and predicate device.			

6. Summary of Non-Clinical Performance Testing

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.

- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Test for in vitro cytotoxicity
- ISO 10993-7:2008 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
- ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Test for irritation and delayed-type hypersensitivity
- 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
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
- USP <85>Bacterial Endotoxins Test

7. Summary of Clinical Performance Testing

No clinical study is included in this submission.

8. Conclusion

Based on comparison and analysis above, the proposed Stone Retrieval Balloon Catheter is determined to be Substantially Equivalent (SE) to the predicate device.