March 21, 2022

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

Re: K212999
Trade/Device Name: Multi-Functional Electrosurgical Knife
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: KNS
Dated: February 11, 2022
Received: February 17, 2022

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,

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K212999

Device Name
Single Use Electrosurgical Knife

Indications for Use *(Describe)*
The Single Use Electrosurgical Knife has been designed to be used with flexible endoscopes to cut tissue using high-frequency current within the digestive tract.

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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# Exhibit #8 510(k) Summary

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

**1. Date of Preparation:** 08/18/2021

**2. Sponsor Identification**

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

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**3. Identification of Proposed Device**

Trade Name: Multi-Functional Electrosurgical Knife
Common Name: Single Use Electrosurgical Knife
(Model: EKM-417D, EKM-425D)

Regulatory Information
Regulation Number: 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulation Class: II
Product Code: KNS
Product Code Name: Unit, Electrosurgical, Endoscopic (with or without accessories)
Device Panel: Gastroenterology/Urology

Indication for Use Statement
The Single Use Electrosurgical Knife has been designed to be used with flexible endoscopes to cut tissue using high-frequency current within the digestive tract.

Device Description
The device is an endoscopic electrosurgical knife for Endoscopic Submucosal Dissection (ESD). The Single Use Electrosurgical Knife is used with flexible endoscopes to cut tissue using high-frequency current within the digestive tract.

It is recommended to use an ERBE VIO-200s electrosurgical unit to supply power to the device.

The list of compatible endoscopes is as below:

510(k) Summary

| Model | Minimum endoscope working channel Φ(mm) | Maximum endoscope working length (mm) |
|---|---|---|
| EKM-417D | Φ2.8 | 2300 |
| EKM-425D | Φ2.8 | 2300 |

**4. Identification of Predicate Devices**

Primary Predicate Device

510(k) Number: K171158

Product Name: Single Use Electrosurgical Knife

Manufacturer: Olympus Medical Systems Corporation

Additional Predicate Device 1

510(k) Number: K092309

Product Name: Single Use Electrosurgical Knife Series

Manufacturer: Olympus Medical Systems Corporation

Reference Device 2

510(k) Number: K083608

Product Name: ERBE Hybrid Knife

Manufacturer: ERBE USA, Inc.

**5. Technical Characteristics of the Device Compared to Predicate Device**

The Single Use Electrosurgical Knife and the predicate Olympus Single Use Electrosurgical Knife have identical intended use in the digestive tract. They are designed to be used with flexible endoscopes to cut tissue using high-frequency current within the digestive tract. The Single Use Electrosurgical Knife combines the two commonly used predicate Olympus DualKnife and ITKnife2 (K171158 and K092309), with two cutting heads that can move relative to each other and function independently without affecting each other. The O cutting knife diameter, maximum insertion portion diameter, minimum channel diameter and outer sheath tube material of the Single Use Electrosurgical Knife are different from that of the predicate Olympus Single Use Electrosurgical Knife (K171158 and K092309).

Additionally, the proposed device has similar intended use as additional reference Device 2 (ERBE HYBRID KNIFE, K083608) in cutting tissue using high-frequency current. Athough, there are minor differences in size/shape, bench testing of cutting performance has demonstrated that these differences do not affect the cutting performance.

| Item | Proposed Device | Primary Predicate Device K171158 | Additional Predicate Device1 K092309 | Reference Device2 K083608 | Similarities and Differences |
|---|---|---|---|---|---|
| Device name | Single Use Electrosurgical Knife | Single Use Electrosurgical Knife | Single Use Electrosurgical Knife Series | ERBE Hybrid Knife | Identical |

510(k) Summary

| | | | | | |
|---|---|---|---|---|---|
| Product code | KNS | KNS | KNS | FQH and GEI | Proposed Device is identical to Primary Predicate Device 1& Additional Predicate Device2, and different to reference Device2 |
| Regulation number | 876.4300 | 876.4300 | 876.4300 | 880.5475 | Proposed Device is identical to Primary Predicate Device 1& Additional Predicate Device1, and different to Reference Device2 |
| Maximum insertion portion diameter | ≤2.4mm | φ2.7mm | φ2.6mm | φ2.6mm | Similar. The Proposed Device and the predicate device are all suitable for φ2.8mm endoscope clamp channel. The difference does not affect the device compatibility with endoscope, refer to the bench testing. |
| Minimum channel diameter | φ2.8mm | φ2.8mm | φ2.8mm | φ2.8mm | Identical |
| Outer sheath tube material | HDPE | PTFE | PTFE | Unknown plastic | Similar; the proposed device and predicate consist of plastic outer sheaths. All materials meet the requirements of biocompatibility and electrical performance. |

**6. Performance Data**

Performance test was performed on the proposed device and predicate devices and the test result demonstrated that there was no significant difference between them. The test include following items:

- Cutting performance of digestive tract mucosa

- Cutting performance of tissue
- Thermal damage performance of tissue
- Endoscope compatibility
- General durability
- Product appearance
- Operational flexibility
- Smoothness of movement

Additional testing was provided to support conformance to the latest revision.

- IEC 60601-1:2005+A1:2012 Medical electric equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electric equipment - Part 1-2: General requirements for basic safety and essential performance collateral standard: Electromagnetic Disturbances requirements and tests
- IEC 60601-2-2:2017 Medical electric equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
- IEC 60601-2-18:2009 Medical electric equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

**7. Biocompatibility**

Testing was conducted to evaluate the device's biocompatibility in accordance with the recommendations of ISO 10993. The following biocompatibility studies were conducted on the final, finished, EO sterilized device and in accordance with the GLP requirements: cytotoxicity, intracutaneous reactivity, sensitization, acute systemic toxicity and pyrogen testing.

**8. Sterilization and Shelf Life**

The Single Use Electrosurgical Knife is sterilized with EO to a sterility level of SAL $10^{-6}$.

Shelf life: 3 years

**9. Clinical Test Conclusion**

No clinical evidence was required to support SE.

**10. Substantially Equivalent (SE) Conclusion**

Anrei Medical (Hangzhou) Co., Ltd has demonstrated that the proposed Single Use Electrosurgical Knife is substantially equivalent to the currently marketed Olympus predicate devices and can be safely and effectively used for its proposed indications.