May 14, 2020

Anrei Medical (Hangzhou) Co., Ltd.
℅ Ray Wang
Official Correspondent
Beijing Believe-Med Technology Service Co., Ltd.
R912, B#15, XiYueHui, No.5, YiHe North Road
FangShan District
Beijing, 102401
CHINA

Re: K192048
Trade/Device Name: Single Use Endoscope Valves Set
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODC
Dated: April 13, 2020
Received: April 15, 2020

Dear Ray Wang:

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)*

K192048

Device Name
Single Use Endoscope Valves Set

Indications for Use *(Describe)*

The Single Use Endoscope Valves Set are used to fit to multiple endoscope working channels/ports to enable an endoscope operator control the function of the working channels/ports and prevent retrograde flow of the fluids, gases, and other materials.

The Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure.

The Suction Valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.

The Biopsy Valve is intended to accommodate various sizes of endoscopic accessory instruments while still providing a seal around the instrument channel inlet.

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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Tab #3 510(k) 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: K192048

1. Date of Preparation: 04/13/2020

2. Sponsor Identification

Anrei Medical (HangZhou) Co., Ltd.
No.3 Ave 8, HEDA, HangZhou City, ZheJiang, China 310018

Contact Person: Yang HuiBing
Position: Regulations & Quality System Director
Tel: +86-571-8691333 ext. 8658
Fax: +86-571-87603502
Email: **huibing.yang@anrei.com.cn**

3. Designated Submission Correspondent

Mr. Ray Wang

Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd., FangShan District, BeiJing, China 102401

Tel: +86-18910677558
Fax: +86-10- 56335780
Email: **ray.wang@believe-med.com**

4. Identification of Proposed Device

Trade Name: Single Use Endoscope Valves Set
Common Name: Endoscope and Accessories
Model(s): AMH-EV-01; AMH-EV-02; AMH-EV-03

Regulatory Information
Classification Name: Endoscope and Accessories
Classification: 2
Product Code: ODC
Regulation Number: 21 CFR 876.1500
Review Panel: Gastroenterology/Urology;

Indications for Use Statement:
The Single Use Endoscope Valves Set are used to fit to multiple endoscope working channels/ports to enable an endoscope operator control the function of the working channels/ports and prevent retrograde flow of the fluids, gases, and other materials.
The Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure.
The Suction Valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.
The Biopsy Valve is intended to accommodate various sizes of endoscopic accessory instruments while still providing a seal around the instrument channel inlet.

Device Description
The Single Use Endoscope Valves Set collects three types of valve products into one package unit, and which are used to fit to multiple endoscope working channels/ports to enable an endoscope operator control the function of the working channels/ports and prevent retrograde flow of the fluids, gases, and other materials.
This is single-use device and supplied sterile.
There are three main components included, which are Air/Water Valve, Suction Valve and Biopsy Valve.
The Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure.
The Suction Valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.
The Biopsy Valve is intended to accommodate various sizes of endoscopic accessory instruments while still providing a seal around the instrument channel inlet.
There are three models for fitting to varied endoscopes as AMH-EV-01; AMH-EV-02; AMH-EV-03. The main differences between models are physical size of components for varied endoscopes interface, but they share same indication for use, materials and components form.

5. Identification of Predicate Device(s)

510(k) Number: K102409
Product Name: DEFENDO Disposable Air/Water Valve for GI Endoscopes

510(k) Number: K102581
Product Name: DEFENDO Disposable Suction Valve for GI Endoscopes

510(k) Number: K090851
Product Name: DEFENDO Biopsy Valve (Model #100301 and I00302)

6. Non-Clinical Test Discussion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device.

Biological Testing was conducted as following standards, the results shown that the proposed devices has same biocompatibility with predicate devices.
ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity.
ISO 10993-10:2010, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity;

Sterile Testing was conducted as following standards, the results shown that the proposed devices has same sterilization performance with predicate devices.
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
ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
USP40_NF35<85> Bacterial Endotoxins Test.

Package Testing was conducted as following standards, the results shown that the proposed devices has same package performance with predicate devices.
ASTM D 3078-02(2013) Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
ASTM F 1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
DIN 58953-6:2016 Sterilization-Sterile supply – Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilizaed.
ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1140/F1140M-13 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages

The shelf Life validation was conducted as following standard, the results shown that the proposed

devices meet the requirements of claimed shelf life.
ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

The performance testing was conducted for the performance of tensile strength, water and gas flow rates, pressure maintenance, water and air flow leakage, backflow, insertion and removal, endoscope compatibility and insertion force etc., this testing was a test that compares the proposed device with the predicate devices. The results shown that the proposed device has same performance with predicate device.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device(s)	Predicate Device(K102409)	Predicate Device(K102581)	Predicate Device (K090851)	Remark
Device name	Single Use Endoscope Valves Set	DEFENDO Disposable Air/Water Valve for GI Endoscopes	DEFENDO Disposable Suction Valve for GI Endoscopes	DEFENDO Biopsy Valve (Model #100301 and I00302)	/
Classification Name	Endoscope and accessories	Endoscope and accessories	Endoscope and accessories	Endoscope and accessories	SAME
Regulation Number	876.1500	876.1500	876.1500	876.1500	SAME
Indications for Use	The Single Use Endoscope Valves Set are used to fit to multiple endoscope working channels/ports to enable an endoscope operator control the function of the working channels/ports and prevent retrograde flow of the fluids, gases, and other materials. The Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure. The Suction Valve is intended to be used to control the suction function on an endoscope during a GI	The DEFENDO Disposable Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure.	The DEFENDO Disposable Suction Valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.	DEFENDO Disposable Biopsy Valve is indicated for covering the endoscope biopsy port during an endoscopy procedure. The valve provides access for endoscopic device passage and exchange, helps maintain sufflation, and minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure.	SAME

	endoscopic procedure. The Biopsy Valve is intended to accommodate various sizes of endoscopic accessory instruments while still providing a seal around the instrument channel inlet.				
Prescription/OTC	Prescription Use	Prescription Use	Prescription Use	Prescription Use	SAME
Components	Air/Water Valve, Suction Valve, Biopsy Valve	Air/Water Valve	Suction Valve	Biopsy Valve	SAME
Supplied Sterile	Yes	Yes	Yes	Yes	SAME
Single use	Yes	Yes	Yes	Yes	SAME
Feature	Sterile and single-use; Compatible with multiple endoscope working channels/ports; Enable an endoscope operator control the function of the working channels/ports and prevent retrograde flow of the fluids, gases, and other materials;	Sterile and single-use; Compatible with multiple endoscope working channels/ports; Enable an endoscope operator control the function of the working channels/ports and prevent retrograde flow of the fluids, gases, and other materials;	Sterile and single-use; Compatible with multiple endoscope working channels/ports; Enable an endoscope operator control the function of the working channels/ports and prevent retrograde flow of the fluids, gases, and other materials;	Sterile and single-use; Compatible with multiple endoscope biopsy port during an endoscopy procedure	SAME
Materials	Air/Water Valve: ABS+Silica+SUS304 Suction Valve: ABS+Silica+SUS304	Not Available	Not Available	Not Available	Difference

	Biopsy Valve: Silica				
Principle of operation	The principal axis of Air/Water valve is equipped with different sizes of sealing rings, which use spring to control advance and retreat, and control the water supply and air supply function of endoscope in endoscopic surgery; The principal axis of Suction valve is equipped with different sizes of sealing rings, which use spring to control advance and retreat, and endoscope suction function in endoscopic surgery; The Biopsy Valve will close fitting with the forceps port to prevents gas and liquid from overflowing from the forceps port, the cross cutting on the surface can reduce friction between the instrument and the forceps port.	The Air/Water valve can be controlled advance and retreat, and it can control the water supply and air supply function of endoscope in endoscopic surgery;	The products is attached to the suction cylinder of the endoscope. When the valve is depressed, suction function on the endoscope is activated allowing for the suctioning of fluid through the stem of the valve where it flows into the suction pump canister.	The valve provides access for endoscopic device passage and exchange, helps maintain sufflation, and minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure.	SAME
Compatibility	Olympus	Olympus 140/160/180/240/260	Olympus 140/160/180/240/260	Olympus, Fujinon, Pentax	Difference

	140/160/180/240/260/290 series; Fujinon 500 and 600 series; Pentax i10 and 90 series.	series endoscopes	series endoscopes	Endoscopes	
Packaging	The air/water valves, suction valve and biopsy valve are housed in a single tray and packaged in sealed initial package.	Not Available	Suction and air/water valves are housed in a single tray and packaged in a sealed Tyvek pouch	Not Available	SAME
Sterilization Method	EO	Not Available	EO	Not Available	SAME
Shelf Life	3 year	Not Available	1 year	Not Available	Difference
Biocompatibility	Cytotoxicity, Sensitization and Irritation	Not Available	Cytotoxicity, Sensitization and Irritation	Not Available	SAME
Difference Analysis Compatibility: The proposed device has different compatibility scope than predicate device, for this different, the performance testing to the proposed device has included compatibility testing to all compatible endoscopes claimed, the testing results shown that the proposed devices are compatibility with all endoscopes claimed. So, this different does not affect the safety and effectiveness of proposed device. Shelf Life: The proposed device has different shelf life than predicate device, for this different, the shelf life validation of 3 years has been conducted, which included performance testing after accelerated aging and real-time aging. The testing results shown that 3 years shelf life would not affect the performance of proposed device. So, this different does not affect the safety and effectiveness of proposed device. Materials: Because the detail materials information of predicated are not available, so it could be considered as different. For this different, the Biocompatibility testing has been conducted, and the test results shown that the materials difference would not affect the safety of proposed device. So, this different does not affect the safety and effectiveness of proposed device.					

9. Substantially Equivalent (SE) Conclusion

The conclusions drawn from the nonclinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device predicate