September 6, 2019

Smartdata Suzhou Co., Ltd
% Anna Reifschneider
Responsible Third-Party Official
Accelerated Device Approval Services, LLC
6800 S.W. 40th Street, Ste. 444
Ludlum, FL 33155-3708

Re: K191366
Trade/Device Name: Vacutore Air/Water Bottle Tubing
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCX
Dated: August 23, 2019
Received: August 26, 2019

Dear Anna Reifschneider:

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,

for
Martha W. Betz, 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)*
K191366

Device Name

Vacutore® Air/Water Bottle Tubing

Indications for Use *(Describe)*

The Vacutore® Air/Water Bottle Tubing (Model GAR025, GAR072 & GAR076) is to connect an air/CO2 source, a sterile water source (water bottle), and an endoscope to supply air/CO2 and water during gastrointestinal endoscopic procedures. It is a 24-hour multi-patient use device.

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

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

1. Submission Sponsor

Submitter's Name:	Smartdata Suzhou Co., Ltd
Submitter's Address:	4f, Block 7, 198#, Jinshan Rd New District Suzhou, Jiangsu 215011 CHINA
Establishment Registration No.:	3008058134

2. Sponsor Contact

Contact Person:	Cindy Ye General Manager
Telephone:	+86 512 6598 3722 +852 6393 5184
Email:	cindy.ye@smartdatamedical.com

3. Date Prepared

15th Mar 2019

4. Device Identification

Trade Device Name:	Vacutore® Air/Water Bottle Tubing
Common Device Name:	Air/Water Tubing for Endoscope
Classification Name:	OCX - Endoscopic Irrigation/Suction System
Regulation Number:	876.1500
Classification	2

5. Predicate Device Identification

Predicate Device 510(k) No.:	K093665
Predicate Device Trade Name:	Endo SmartCap™
Predicate Device Product Code:	FAJ

6. Device Description:

The Vacutore® Air/Water Bottle Tubing is intended for 24-hour multi-patient use. Air/water bottle tubing is supplied in sterile. Table 1 shows the components included in the application.

Table 1 – Components included in the application

Components	Qty	Classification Name	Regulation Number	Classification
Vacutore® Air/Water Bottle Tubing (GAR025)	1	OCX - Endoscopic Irrigation/Suction System	876.1500	2
Vacutore® Air/Water Bottle Tubing (GAR072)	1	OCX - Endoscopic Irrigation/Suction System	876.1500	2
Vacutore® Air/Water Bottle Tubing (GAR076)	1	OCX - Endoscopic Irrigation/Suction System	876.1500	2

The Vacutore® Air/Water Bottle Tubing is manufactured for use in conjunction with sterile water bottle, and together with Olympus 160 and Pentax 90 series endoscopes. The air/water bottle tubing is individually packed in sealed package, sold as a sterile device. The air/water bottle tubing is designed to be attached to the air/water port of the endoscopes to provide irrigation through the air/water channel to the distal end of endoscope.

According to the Medical Device Recalls database in FDA website, no product recall was found for the predicate device. According to the FDA MAUDE database, safety issues on fluid leakage and backflow were identified. In the performance test, the leakage test are conducted for verification.

There were no prior submissions for the Vacutore® Air/Water Bottle Tubing.

7. Intended Use:

The Vacutore® Air/Water Bottle Tubing (Model GAR025, GAR072 & GAR076) is to connect an air/CO_2 source, a sterile water source (water bottle), and an endoscope to supply air/CO_2 and water during gastrointestinal endoscopic procedures. It is a 24-hour multi-patient use device.

8. Technological Characteristics

Table 2 summaries the Vacutore® Air/Water Bottle Tubing technological characteristics as compared to the predicate device from Endo SmartCap™.

Table 2 Summary of design, features and principles of operation between the Vacutore® Air/Water Bottle Tubing (GAR025, GAR072 & GAR076) technological characteristics as compared to the predicate devices.

Specification	**Predicate Device**	**Proposed Device**	**Substantial Equivalence**
Device name	**Endo SmartCap™**	**Vacutore® Air/Water Bottle Tubing**	N/A
K number	K093665	---	N/A
Manufacturer	Medivators, Inc.	Smartdata Suzhou Co., Ltd	N/A
Product code	FAJ	OCX	N/A

Classification	2	2	Identical
Regulation No	876.1500	876.1500	Identical
Regulation Name	Endoscope and accessories	Endoscope and accessories	Identical
Supplied Sterile	Yes	Yes	Identical
Compatibility	Pentax GI Endoscope	GAR025: Olympus 160 series endoscope GAR072 & GAR076: Pentax 90 series endoscope	Substantial Equivalent
Indications for Use	ENDO SMARTCAP™ Tubing is intended to be used with an air or CO_2 source and/ or pump along with a sterile water source to supply air or CO_2 and sterile water to an gastrointestinal endoscope during endoscopic procedures	The Vacutore® Air/Water Bottle Tubing (Model GAR025, GAR072 & GAR076) is to connect an air/CO_2 source, a sterile water source (water bottle), and an endoscope to supply air/CO_2 and water during gastrointestinal endoscopic procedures. It is a 24-hour multi-patient use device.	Substantial Equivalent
Environment of Use	Hospital and or clinics	Hospital and or clinics	Identical
Material	Methyl methacrylate-acrylonitrile-butadiene-styrene copolymer, Polycarbonate, Polyethylene, Polyvinyl Chloride, Thermoplastic Elastomer, Nitrile Butadiene Rubber	Thermoplastic polyurethanes, Polyvinyl Chloride, Silicone, Polyoxymethylene, Polycarbonate, stainless steel 304, Acrylonitrile Butadiene Styrene	Substantial Equivalent
Packaging	Each model packed separately in a seal pouched	Each model packed separately in a seal pouched	Identical
Manufacturing method	Injection moulding	Injection moulding	Substantial Equivalent
Sterilization	EO gas	EO gas	Identical
Shelf Life	Three years	Three years	Identical

9. Non-Clinical Performance Data

Smartdata performed bench testing to support substantial equivalence. The following testing were performed on Smartdata samples from initial production lots, including sterilization.

9.1 Performance Test

9.1.1 Vacutore® Air/Water Bottle Tubing (GAR025, GAR072 and GAR076)

9.1.1.1 Assembling Integrity
9.1.1.2 Endoscope Compatibility
9.1.1.3 Compatibility with Bottle
9.1.1.4 Two-Way Valve Integrity
9.1.1.5 Flow Clamp Test
9.1.1.6 Water Flow Test
9.1.1.7 Back Flow Performance Test

9.2 Sterilization

Vacutore® Air/Water Bottle Tubing is sold in sterile package, like the Medivators predicate devices. The subject device has been sterilized in a validated EO sterilization cycle. The EO sterilization cycle has a Sterility Assurance Level (SAL) of 10^{-6}. EO residuals on the components are below the maximum levels defined in ANSI/AAMI/ISO 10993-7:2008 *Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide sterilization residuals.* The Vacutore® Air/Water Bottle Tubing, and the predicate devices, are not labeled as pyrogen-free because they do not have any blood or cerebrospinal fluid contact.

9.3 Shelf Life

The Vacutore® Air/Water Bottle Tubing has a three (3) year expiration date, based on the design and material equivalence to the predicate devices and existing sterile barrier data from Smartdata existing packaging. The Vacutore® Air/Water Bottle Tubing is packaged in a paper/film pouch respectively like other sterile products Smartdata currently manufactures. These pouches have been tested by Sanitation Environment Technology Institute, Soochow University ,which is an CNAS accredited laboratory. The tests conducted including accelerated aging, seal strength, dye penetration, microbial barrier properties, vacuum leak test and the sterility test. Smartdata conducted the performance test after the accelerated aging process. The test result can imply that the air/water bottle tubing can provide and maintain a sterile barrier and its intended performance for at least three (3) years.

9.4 Biocompatibility

The biocompatibility of the Vacutore® Air/Water Bottle Tubing was conducted in accordance with the FDA guideline “Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process””. It included the following tests.

- Acute Systemic Toxicity Test
- In Vitro Cytotoxicity
- Skin sensitization
- Irritation

The air/water bottle tubing is classified as surface device with mucosal membrane contact for a limited duration (not more than 24 hours). The test result shows that the air/water bottle tubing is biocompatible.

9.5 Barrier Integrity and Simulated Use Testing

The barrier integrity and simulated use testing of Vacutore® Air/Water Bottle Tubing was conducted. The test result can imply that the air/water valve in the endoscope provide sufficient back-backflow prevention to the Vacutore® Air/Water Bottle Tubing and verified 24-hour multi-patient use

10. Clinical Testing

Similar devices have been on the market for many years with proven safety and efficacy for the use of the device. These devices have no direct patient contact. Based on this history and the use of the device, clinical testing was not necessary to support substantial equivalence data. The non-clinical testing performed supports safety and efficacy of the devices and provides data to show substantial equivalence to the predicate device.

11. Conclusion

Vacutore® Air/Water Bottle Tubing has the same intended use as the predicate devices.

Based on the technological characteristics and overall performance of the devices in bench testing, Smartdata believes that no significant differences exist between the proposed air/water bottle tubing and the predicate devices.

The Vacutore® Air/Water Bottle Tubing does not raise any new issues of safety and effectiveness.

From a clinical perspective and comparing design specifications, the Vacutore® Air/Water Bottle Tubing, and the predicate device are substantially equivalent.