June 7, 2019

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

Re: K191231
Trade/Device Name: Andorate Valves Set (GAR037) and Andorate Auxiliary Water Connector (GAR048)
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODC, OCX
Dated: May 3, 2019
Received: May 8, 2019

Dear Thomas Schorre:

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
Shani P. Haugen, Ph.D.
Acting, Assistant Division 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)*

K191231

Device Name

Andorate Valves Set (GAR037) and Andorate Auxiliary Water Connector (GAR048)

Indications for Use *(Describe)*

The Andorate Auxiliary Water Connector (Model GAR048) is used in conjunction with irrigation tubing (not supplied), intended to provide irrigation via irrigation fluids such as sterile water supplied to the Pentax 90 series endoscope during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump.

The disposable Andorate Valves Set (Model GAR037) consists of one suction valve, one air/water valve and one biopsy valve.

- The Andorate Disposable Suction Valve is used to control the suction function of an endoscope (for Pentax 90 series Endoscope) during a GI Endoscopic procedure.

- The Andorate Disposable Air/Water valve is used to control the air/water function of an endoscope (for Pentax 90 series Endoscope) during a GI Endoscopic procedure.

- The Andorate Disposable biopsy valve is used to cover the endoscope biopsy port during an endoscopy procedure. In addition, the valve provides access for endoscopic device passage and exchange, helps maintain insufflation and minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure.

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.

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510(k) Summary

1. Submission Sponsor

Submitter's Name: Smartdata Suzhou Co., Ltd

Submitter's Address: 4f, Block 7, 198#, Jinshan Rd
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CHINA

Establishment Registration No.: 3008058134

2. Sponsor Contact

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3. Date Prepared

June 6th, 2019

4. Device Identification

Trade Device Name: Andorate® Auxiliary Water Connector (GAR048)
Product code: OCX
Classification Name: Endoscope and Accessories
Regulation Number: 21 CFR 876.1500
Classification: II

Trade Device Name: Andorate® Valves Set (GAR037)
Product code: ODC
Classification Name: Endoscope and Accessories
Regulation Number: 21 CFR 876.1500
Classification: II

5. Predicate Device Identification

Predicate Device 510(k) No.: K092429
Predicate Device Trade Name: ENDOGATOR
Predicate Device Product Code: FEQ

Predicate Device 510(k) No.: K102581
Predicate Device Trade Name: DEFENDO™ Disposable Suction Valve
Predicate Device Product Code: ODC

Predicate Device 510(k) No.: K102409
Predicate Device Trade Name: DEFENDO™ Disposable Air/Water Valve
Predicate Device Product Code: ODC

Predicate Device 510(k) No.: K090851
Predicate Device Trade Name: DEFENDO™ Disposable Biopsy Valve
Predicate Device Product Code: ODC

6. Device Description:

The Andorate® Valves Set and Andorate® Auxiliary Water Connector are intended for single-use and are supplied sterile. Single-use valves sets and auxiliary water connector help preventing potential safety risks and eliminate the need for manual cleaning and reprocessing. The valves set and auxiliary water connector are easily incorporated into infection prevention policies as a single use item. Table 1 shows the components included in the application.

The Andorate® Auxiliary Water Connector is manufactured for use in conjunction with irrigation tubing, and together with Pentax 90 series endoscope. The auxiliary water connector is individually packed in sealed package, sold as a sterile device. The auxiliary water connector is designed to be attached to the auxiliary water port of the endoscopes. The auxiliary water connector consists of a backflow valve which prevent the backflow of water or biomaterials from the endoscope to the sterile water bottle.

The Andorate® Valves Set is manufactured for use with Pentax 90 series endoscope. The suction, air/water, and biopsy valves are housed in a single tray and packaged in sealed packed. The valves set is sold as a sterile device.

- The Suction Valve component of the Andorate® Valves Set is designed to be attached to the suction port of the endoscope and the air/water valve is designed to be attached to the air/ water port of the endoscope. The activation of the suction valve allows the user to aspirate excess fluids or other debris obscuring the endoscopic image, while the activation of the air/ water valve allows the user to control air and water flow to assist in cleansing the lens during procedures.

- The Biopsy Valve component of the Andorate® Valves Set is intended to cover the endoscope biopsy port during an endoscopy procedure. In addition, the valve provides access for endoscopic device passage and exchange, helps maintain insufflation and minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure.

The subject devices in this submission have the same operation and method of action as the predicate devices. In the submission, Andorate® Valves Set and Andorate® Auxiliary Water Connector are the only subject device. This submission does not include irrigation tubing or irrigation pump.

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

There were no prior submissions for the Andorate® valves set and auxiliary water connector.

7. Intended Use:

The Andorate® Auxiliary Water Connector (GAR048) is used in conjunction with irrigation tubing (not supplied), intended to provide irrigation via irrigation fluids such as sterile water supplied to the Pentax 90 series endoscope during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump.

The Suction Valve component of the Andorate® Valves Set (GAR037) is used to control the suction

function of an endoscope (for Pentax 90 series Endoscope) during a GI Endoscopic procedure.
The Disposable Air/Water Valve component of the Andorate® Valves Set (GAR037) is used to control the air/water function of an endoscope (for Pentax 90 series Endoscope) during a GI Endoscopic procedure.
The Biopsy Valve component of the Andorate® Valves Set (GAR037) is used to cover the endoscope biopsy port during an endoscopy procedure. In addition, the valve provides access for endoscopic device passage and exchange, helps maintain insufflation and minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure.

8. Technological Characteristics

The following tables are summaries of the subject device's technological characteristics as compared to the predicate devices.

Comparison table for the ANDORATE® Valves Set					
Specification	**DEFENDO Disposable Suction Valve**	**DEFENDO Disposable Air/Water Valve**	**DEFENDO Disposable Biopsy Valve**	**ANDORATE® Valves Set**	**Substantial Equivalence**
K number	K102581	K102409	K090851	K191231	n/a
Manufacturer	Medivators, Inc.	Medivators, Inc.	Medivators, Inc.	ANDORATE® Valves Set	n/a
Product code	ODC	ODC	ODC	ODC	Identical
Classification	II	II	II	II	Identical
Regulation No	876.1500	876.1500	876.1500	876.1500	Identical
Regulation Name	Endoscope and accessories	Endoscope and accessories	Endoscope and accessories	Endoscope and accessories	Identical
Supplied Sterile	Yes	Yes	Yes	Yes	Identical
Indications for Use	The DEFENDO Disposable Suction valve is intended to be used control the suction function of an endoscope during a GI Endoscopic procedure.	The DEFENDO Disposable Air/Water valve is intended to be used control the air/water function of an endoscope during a GI Endoscopic procedure.	The DEFENDO Disposable biopsy valve is intended to be cover the endoscope biopsy port during an endoscopy procedure. In addition, the valve provides access for endoscopic device passage and exchange, helps maintain insufflation and minimizes leakage of biomaterial from the biopsy port throughout the	The Andorate® Auxiliary Water Connector (GAR048) is used in conjunction with irrigation tubing, intended to provide irrigation via irrigation fluids such as sterile water supplied to the Pentax 90 series endoscope during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump. The Suction Valve component of the Andorate® Valves Set (GAR037) is used to control the suction function of an endoscope (for Pentax 90 series Endoscope) during a GI Endoscopic procedure. The Disposable Air/Water Valve component of the Andorate® Valves Set (GAR037) is used to control the air/water function of an endoscope (for Pentax 90 series Endoscope) during a GI Endoscopic procedure. The Biopsy Valve component of the Andorate® Valves Set (GAR037) is used to cover the endoscope biopsy port during an endoscopy procedure. In addition, the valve provides access for endoscopic device passage and exchange, helps maintain insufflation and minimizes leakage of	Substantial Equivalence

Comparison table for the ANDORATE® Valves Set					
Specification	**DEFENDO Disposable Suction Valve**	**DEFENDO Disposable Air/Water Valve**	**DEFENDO Disposable Biopsy Valve**	**ANDORATE® Valves Set**	**Substantial Equivalence**
			endoscopic procedure	biomaterial from the biopsy port throughout the endoscopic procedure.	
Environment of Use	Hospital and/or clinics	Hospital and/or clinics	Hospital and/or clinics	Hospital and/or clinics	Identical
Single Use, Disposable	Yes	Yes	Yes	Yes	Identical
Material	Nitrile Butadiene Rubber, Thermoplastic Elastomer, Polycarbonate, Styrene ethylene-butene-styrene block copolymer, High impact polystyrene, stainless steel 304	.		**Suction Valve component of the Andorate® Valves Set:** Polycarbonate, Acrylonitrile Butadiene Styrene, silicone, Stainless Steel 304	Substantial Equivalence
Material		Thermoplastic Elastomer, Polycarbonate, Stainless Steel 304		**Air/Water Valve component of the Andorate® Valves Set:** Acrylonitrile Butadiene Styrene, silicone, Stainless Steel 304	Substantial Equivalence
Material			Thermoplastic Elastomer	**Biopsy Valve component of the Andorate® Valves Set:** Silicone	Substantial Equivalence
Packaging	Suction, air /water and biopsy valves are housed in a	Suction, air /water and biopsy valves are housed in a single tray and	Suction, air /water and biopsy valves are housed in a	Suction, air /water and biopsy valves are housed in a single tray and packaged in a sealed pouched	Identical

Comparison table for the ANDORATE® Valves Set					
Specification	**DEFENDO Disposable Suction Valve**	**DEFENDO Disposable Air/Water Valve**	**DEFENDO Disposable Biopsy Valve**	**ANDORATE® Valves Set**	**Substantial Equivalence**
	single tray and packaged in a sealed pouched	packaged in a sealed pouched	single tray and packaged in a sealed pouched		
Manufacturing method	Injection moulding and overmoulding.			**Suction Valve component of the Andorate® Valves Set:** Injection moulding and overmoulding.	Substantial Equivalence
Manufacturing method		Injection molded		**Air/Water Valve component of the Andorate® Valves Set:** Injection moulding	Substantial Equivalence
Manufacturing method			Injection moulding	**Biopsy Valve component of the Andorate® Valves Set:** Injection moulding	Substantial Equivalence
Sterilization	EO gas	EO gas	EO gas	EO gas	Identical
Shelf Life	Three years	Three years	Three years	Three years	Identical
Compatibility	Pentax GI Endoscope	Pentax GI Endoscope	Pentax GI Endoscope	Pentax 90 series Endoscope	Substantial Equivalence

Comparison table for the ANDORATE® Auxiliary Water Connector			
Specification	**ENDOGATOR**	**ANDORATE® Auxiliary Water Connector**	**Substantial Equivalence**
K number	K092429	K191231	n/a
Manufacturer	Medivators, Inc.	ANDORATE® Valves Set	n/a
Product code	FEQ	OCX	Identical
Classification	II	II	Identical
Regulation No	21 CFR 876.1500	21 CFR 876.1500	Identical
Regulation Name	Endoscope and accessories	Endoscope and accessories	Identical
Supplied Sterile	Yes	Yes	Identical
Indications for Use	The ENDOGATOR® system is intended to provide irrigation via sterile water during GI endoscopic procedures when used in conjunction with an irrigation pump (or cautery unit).	The Andorate® Auxiliary Water Connector (GAR048) is used in conjunction with irrigation tubing, intended to provide irrigation via irrigation fluids such as sterile water supplied to the Pentax 90 series endoscope during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump. The Suction Valve component of the Andorate® Valves Set (GAR037) is used to control the suction function of an endoscope (for Pentax 90 series Endoscope) during a GI Endoscopic procedure. The Disposable Air/Water Valve component of the Andorate® Valves Set (GAR037) is used to control the air/water function of an endoscope (for Pentax 90 series Endoscope) during a GI Endoscopic procedure. The Biopsy Valve component of the Andorate® Valves Set (GAR037) is used to cover the endoscope biopsy port during an endoscopy procedure. In addition, the valve provides access for endoscopic device passage and exchange, helps maintain insufflation and minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure.	Substantial Equivalence

Comparison table for the ANDORATE® Auxiliary Water Connector			
Specification	**ENDOGATOR**	**ANDORATE® Auxiliary Water Connector**	**Substantial Equivalence**
Environment of Use	Hospital and or clinics	Hospital and or clinics	Identical
Single Use, Disposable	Yes	Yes	Identical
Material	Nitrile Butadiene Rubber, Methyl methacrylate-Acrylonitrile-Butadiene-Styrene Copolymer, Silicone Rubber	Polycarbonate, silicone	Substantial Equivalence
Packaging	Auxiliary water connector is packaged in a sealed pouch.	Auxiliary water connector is packaged in a sealed pouch.	Identical
Manufacturing method	Injection moulding with ultrasonic welding	Injection moulding	Substantial Equivalence
Sterilization	EO gas	EO gas	Identical
Shelf Life	Three years	Three years	Identical
Compatibility	Pentax GI Endoscope	Pentax 90 series Endoscope	Substantial Equivalence
Dimension	Length: 32.14 mm Max. diameter: 15.43 mm	Length: 40.70 mm Max. diameter: 11.73 mm	Substantial Equivalence
Connection port	One side with insertion cylinder with silicone on the top and thread on the bottom: Length: 10.32 mm Diameter: 6.07 mm Diameter of thread: 7.94 mm Other side with female luer lock: Diameter: 7.78 mm	One side with insertion cylinder with silicone ring on the top and thread on the bottom: Length: 10.16 mm Diameter: 6.06 mm Diameter of thread: 7.93 mm Other side with female luer lock: Diameter: 7.77 mm	Substantial Equivalence
Backflow Prevention Design	Diaphragm in the connector allow pressurized water passing through in one-way but not the other way	Diaphragm in the connector allow pressurized water passing through in one-way but not the other way	Substantial Equivalence

The product code of predicate device for the auxiliary water connector (FEQ) is different from the proposed device (OCX). The predicate device ENDOGATOR consist of irrigation accessories (auxiliary water connector, Model: 100242). According to the FDA AccessGUDID system, ENDOGATOR auxiliary water connector (Model: 100242) was classified as product code OCX. Smartdata select the auxiliary water connector (Model: 100242) for the determination of substantial equivalence of proposed auxiliary water connector with the predicate device.

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 Andorate® Valves Set (GAR037) - *Component: Disposable Suction Valve*

- 9.1.1.1 Assembling Integrity
- 9.1.1.2 Endoscope Compatibility
- 9.1.1.3 Depression Force
- 9.1.1.4 Vacuum Leak Test
- 9.1.1.5 Suction Flow Test

9.1.2 Andorate® Valves Set (GAR037) - *Component: Disposable Air/Water Valve*

- 9.1.2.1 Endoscope Compatibility Testing
- 9.1.2.2 Air Leakage Testing
- 9.1.2.3 Assembling Integrity Verification
- 9.1.2.4 Depression Force Testing
- 9.1.2.5 Water Flow Test

9.1.3 Andorate® Valves Set (GAR037) - *Component: Disposable Biopsy Valve*

- 9.1.3.1 Assembling Integrity
- 9.1.3.2 Endoscope Compatibility
- 9.1.3.3 Vacuum Leak Test
- 9.1.3.4 Squeegee Leak Test

9.1.4 Andorate® Auxiliary Water Connector (GAR048)

- 9.1.4.1 Compatibility with irrigation tubing
- 9.1.4.2 Compatibility with endoscope
- 9.1.4.3 Water Flow Test
- 9.1.4.4 Air Leakage Test
- 9.1.4.5 Water Leakage Test
- 9.1.4.6 Backflow Performance Test

9.2 Sterilization

Both the Andorate® Valves Set and Andorate® Auxiliary Water Connector are sold in sterile packaging, like the Medivators' predicate devices. The subject devices have 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 subject devices and predicate devices, are not labeled as pyrogen-free because they do not have any blood or cerebrospinal fluid contact.

9.3 Shelf Life

The Andorate® Valves Set and Andorate® Auxiliary Water Connector have 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 subject devices are packaged in a paper/film pouch respectively like other sterile products that 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 for the valves set and auxiliary water connector after the accelerated aging process. The test result can imply that both the valves set and water auxiliary connector can provide and maintain a sterile barrier and its intended performance for at least three (3) years.

9.4 Biocompatibility

The biocompatibility of the Andorate® Valves Set and Andorate® Auxiliary Water Connector were 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

Both the valves set and auxiliary water connector are classified as surface devices with mucosal membrane contact for a limited duration (not more than 24 hours). The test result shows that both the valves set and auxiliary water connector is biocompatible.

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. Determination of substantial equivalence based on an assessment of performance data

Performance testing was conducted to evaluate and characterize the performance of the subject devices to support a determination of substantial equivalence to the predicate devices. A comparison was made against the predicates, where data was available. The subject devices haveundergone sterility, packaging, biocompatibility, and bench testing to demonstrate that any differences do not raise questions of safety or efficacy. The following tests were performed on the subject devices:

- ISO 10993-5
- ISO 10993-7
- ISO 10993-10
- ISO 10993-11
- ISO 11135-1
- ISO 11138-1
- ISO 11138-2
- ISO 11737-1
- ISO 11737-2
- ASTM D4169-16
- ASTM F1980-16
- ASTM F88/F88M-15
- ASTM F1929-15
- ASTM D3078-02
- AAMI TIR 16

The subject devices were found to have a safety and effectiveness profile that is the same as the predicate devices and is determined to be substantially equivalent. In summary, the subject devices have the following similarities to the predicate devices:

- Has the same indications for use
- Has the same intended use
- Used in the same anatomical site
- Uses the same technological characteristics
- Uses the same principles of operation
- Uses the same sterilization methodology
- Biocompatible for its intended use

12. Conclusion

Smartdata's Andorate® Valves Set and Andorate® Auxiliary Water Connector have 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 valves set and auxiliary water connector, and the predicate devices.

The subject devices do not raise any new issues of safety and effectiveness. From a clinical perspective and comparing design specifications, the subject devices and the predicate device are substantially equivalent.