K182998 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

17 Apr 2019

4. Device Identification

Trade Device Name:	Andorate™ Auxiliary Water Connector
Part No.	GAR027
Common Device Name:	Connector between the tube and endoscope
Classification Name:	Endoscope and accessories
Product Code	OCX – Endoscopic Irrigation/Suction System
Regulation Number:	876.1500
Device Class	2

5. Predicate Device Identification

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

6. Device Description:

The Andorate™ Auxiliary Water Connector is intended for single-use and are supplied sterile. Single-use auxiliary water connector help preventing potential safety risks and eliminate the need for manual cleaning and reprocessing. The auxiliary water connector easily incorporate

into infection prevention policies as a single use item. Table 1 shows the components included in the application.

Table 1 – Components included in the application

Components	Qty	Product Code	Regulation Number	Classification
Andorate™ Auxiliary Water Connector	1	OCX – Endoscopic Irrigation/Suction System	876.1500	2

The Andorate™ Auxiliary Water Connector are manufactured for use in conjunction with irrigation tubing, and together with Olympus 160 series endoscopes. The auxiliary water connector is individually packed in sealed package, sold as a sterile device. In the submission, Andorate™ Auxiliary Water Connector is the only subject device. This submission does not include irrigation tubing or irrigation pump.

The auxiliary water connector are designed to be attached to the auxiliary water port of the endoscopes. The auxiliary water connector consist of a backflow valve which prevent the backflow of water or biomaterials from the endoscope to the sterile water bottle. The backflow performance was tested to ensure it prevents backflow of substances.

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 and backflow test were conducted for verification.

There were no prior submissions for the Smartdata's auxiliary water connector.

7. **Intended Use:**
The Andorate™ Auxiliary Water Connector (Model GAR027) is used in conjunction with irrigation tubing (not supplied), intended to provide irrigation via irrigation fluids such as sterile water supplied to the Olympus 160 series endoscope during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump.

8. **Technological Characteristics**
The following table (Table 2) is summaries of the Andorate™ Auxiliary Water Connector technological characteristics as compared to the predicate device from ENDOGATOR.

Table 2 Summary of design, features and principles of operation between the Andorate™ Auxiliary Water Connector technological characteristics as compared to the predicate device from ENDOGATOR™ – Water Connector for Olympus GI Endoscope

Specification	**Predicate Device**	**Proposed Device**	**Substantial Equivalence**
Device name	**ENDOGATOR (Irrigation Accessories auxiliary water connector)**	**ANDORATE™ Auxiliary Water Connector**	N/A
K number	K092429	---	N/A
Manufacturer	Medivators, Inc. a Cantel Medical Company	Smartdata Suzhou Co., Ltd	N/A

Product code	FEQ	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	Olympus GI Endoscope	Olympus 160 series Endoscope	Similar
Intended 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 (Model GAR027) is used in conjunction with irrigation tubing (not supplied), intended to provide irrigation via irrigation fluids such as sterile water supplied to the Olympus 160 series endoscope during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump.	Identical
Environment of Use	Hospital and or clinics	Hospital and or clinics	Identical
Single Use, Disposable	Yes	Yes	Identical
Material	Methyl methacrylate Acrylonitrile-Butadiene-Styrene, polydimethylsiloxane, Styrene- ethylene-butene-styrene	Polycarbonate, silicone	Similar
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	Similar
Dimension	Length: 30.26 Max. diameter: 12.61	Length: 36.08 mm Max. diameter: 11.73 mm	Similar
Connection port	One side with screw thread: Diameter 1.80 mm Other side with female luer lock: Diameter 7.79 mm	One side with screw thread: Diameter 1.79 mm Other side with female luer lock: Diameter 7.77 mm	Similar
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	Identical
Sterilization	EO gas	EO gas	Identical
Shelf Life	Three years	Three years	Identical

The product code of predicate device (FEG) is different from the proposed device (OCX). The predicate device ENDOGATOR consist of irrigation accessories (auxiliary water connector, Model: 100241). According to the FDA AccessGUDID system, ENDOGATOR auxiliary water connector (Model: 100241) was classified as product code OCX. Smartdata select the auxiliary water connector (Model: 100241) for the determination of substantial equivalence of proposed device with the predicate device

9. Non-Clinical Performance Data

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

9.1 Andorate™ Auxiliary Water Connector (GAR027)

9.1.1 Compatibility with irrigation tubing
9.1.2 Compatibility with endoscope
9.1.3 Water Flow Test
9.1.4 Air Leakage Test
9.1.5 Water Leakage Test
9.1.6 Backflow Performance Test

9.2 Sterilization

The Andorate™ Auxiliary Water Connector is sold in sterile package, like the Medivators predicate device. The auxiliary water connector 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 Smartdata auxiliary water connector, 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 Andorate™ Auxiliary Water Connector have a three (3) year expiration date, based on the design and material equivalence to the predicate device and existing sterile barrier data from Smartdata existing packaging. The Smartdata auxiliary water connector are 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 tested 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 auxiliary water connector after the accelerated aging process. The test result can imply that the 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™ Auxiliary Water Connector 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 (Rectal Irritation Test)

The 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 the 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 device and provides data to show substantial equivalence to the predicate device.

11. Conclusion

Smartdata Andorate™ Auxiliary Water Connector has the same intended use as the predicate device.

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

The Smartdata auxiliary water connector do not raise any new issues of safety and effectiveness.

From a clinical perspective and comparing design specifications, the Smartdata auxiliary water connector, and the predicate device are substantially equivalent.