K181509
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

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3. Date Prepared

6th Jul 2018

4. Device Identification

Trade Device Name:	Endorate™ Valve Sets

Trade Device Name:	Endorate™ Disposable Suction Valve
Common Device Name:	Suction Valve for Endoscope
Product Code Name:	OCX – Endoscopic Irrigation/Suction System
Regulation Number/Name:	876.1500 Endoscope and accessories
Classification	2

Trade Device Name:	Endorate™ Disposable Air/Water Valve
Common Device Name:	Air/Water Valve for Endoscope
Product Code Name:	OCX – Endoscopic Irrigation/Suction System
Regulation Number/Name:	876.1500 Endoscope and accessories
Classification	2

Trade Device Name:	Endorate™ Disposable Biopsy Valve
Common Device Name:	Biopsy Valve for Endoscope
Product Code Name:	ODC - Endoscope Channel Accessory
Regulation Number/Name:	876.1500 Endoscope and accessories
Classification	2

5. Predicate Device Identification

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. General Device Description:

The Endorate™ valve set consists of one suction valve, one air/water valve and one biopsy valve. The Endorate™ device is intended for single-use, and is supplied sterile. Sterile, single-use suction valve, air/water valve and biopsy valve help prevent potential safety risks and eliminate the need for manual cleaning and reprocessing. These valves easily incorporate into infection prevention policies as a single use item. The following table 5.1 shows the components in the Smartdata's valves set.

Table 5.1 Endorate™ Disposable Valves Sets

Components	Qty	Product Code Name	Regulation Number	Classification
Suction Valve	1	ODC – Endoscope Channel Accessory	876.1500	2
Air/Water Valve	1	ODC – Endoscope Channel Accessory	876.1500	2
Biopsy Valve	1	ODC – Endoscope Channel Accessory	876.1500	2

The suction valve 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 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 Endorate™ Disposable Biopsy Valves are manufactured in two configurations - one for use with Olympus®/Fujinon® gastrointestinal endoscopes and the other for use with Pentax® gastrointestinal endoscopes. Both Olympus®/Fujinon® and Pentax® versions are sold as non-sterile device, individually packed.

7. Intended Use:

The Endorate™ Disposable Suction Valve is intended to be used control the suction function of an endoscope during a GI Endoscopic procedure.

The Endorate™ Disposable Air/Water Valve is intended to be used control the air/water function of an endoscope during a GI Endoscopic procedure.

The Endorate™ Disposable Biopsy Valve 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.

8. Technological Characteristics

The following tables (Table 5.2.1, Table 5.2.2 and Table 5.2.3) are a summary of the Endorate™ suction valve, air/water valve and biopsy valve technological characteristics as compared to the predicate device from DEFENDO™.

Table 5.2.1 Summary of design, features and principles of operation between the Endorate™ suction valve technological characteristics as compared to the predicate device from DEFENDO™ – Suction Valve

Specification	Predicate Device	Proposed Device	Substantial Equivalence
Device name	**DEFENDO™ Disposable Suction Valve**	**Endorate™ Disposable Suction Valve**	N/A
K number	K102581	---	N/A
Manufacturer	Medivators, Inc. a Cantel Medical Company	Smartdata Suzhou Co., Ltd	N/A
Product code	ODC	ODC	Identical
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	GI Endoscopes	Olympus® 140/160/180/190/240/260 series Endoscope	Similar

Intended Use	The DEFENDO™ Disposable Suction valve is intended to be used control the suction function of an endoscope during a GI Endoscopic procedure.	The ENDORATE™ Disposable Suction valve is intended to be used control the suction function of an endoscope during a GI Endoscopic procedure.	Identical
Environment of Use	Hospital and or clinics	Hospital and or clinics	Identical
Single Use, Disposable	Yes	Yes	Identical
Material	Polycarbonate, Styrene-ethylene-butene-styrene block copolymer, Stainless Steel 304	Acrylonitrile-Butadiene-Styrene Copolymer, Silicone, Stainless steel 304	Similar
Manufacturing Method	Injection molded	Injection molded	Identical
Packaging	Suction, Air/Water, Biopsy Valves are housed in a single tray and packaged in a sealed pouch.	Suction, Air/Water, Biopsy Valves are housed in a single tray and packaged in a sealed pouch.	Identical
Sterilization	EO gas	EO gas	Identical
Shelf Life	Three years	Three years	Identical

Table 5.2.2 Summary of design, features and principles of operation between the Endorate™ air/water valve technological characteristics as compared to the predicate device from DEFENDO™. – Air/Water Valve

Specification	Predicate Device	Proposed Device	Substantial Equivalence
Device name	**DEFENDO™ Disposable Air/Water Valve**	**Endorate™ Disposable Air/Water Valve**	N/A
K number	K102409	---	N/A
Manufacturer	Medivators, Inc. a Cantel Medical Company	Smartdata Suzhou Co., Ltd	N/A
Product code	ODC	ODC	Identical
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® 140/160/180/240/260 Series GI Endoscopes	Olympus® 140/160/180/190/240/260 series Endoscope	Similar
Intended Use	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 ENDORATE™ Disposable Air/Water valve is intended to be used control the air/water function of an endoscope during a GI Endoscopic procedure.	Identical
Environment of Use	Hospital and or clinics	Hospital and or clinics	Identical
Single Use, Disposable	Yes	Yes	Identical
Material	Polycarbonate, Styrene-ethylene-butene-styrene block copolymer, Stainless Steel 304	Acrylonitrile-Butadiene-Styrene Copolymer, Silicone, Stainless steel 304	Similar
Manufacturing Method	Injection molded	Injection molded	Identical
Packaging	Suction, Air/Water, biopsy valves are housed in a single tray and packaged in a sealed pouch.	Suction, Air/Water, biopsy valves are housed in a single tray and packaged in a sealed pouch.	Identical
Sterilization	EO gas	EO gas	Identical
Shelf Life	Three years	Three years	Identical

Table 5.2.3 Summary of design, features and principles of operation between the Endorate™ biopsy valve technological characteristics as compared to the predicate device from DEFENDO™. – Biopsy Valve

Specification	Predicate Device	Proposed Device	Substantial Equivalence
Device name	**DEFENDO™ Disposable Biopsy Valve**	**Endorate™ Disposable Biopsy Valve**	N/A
K number	K090851	---	N/A

Manufacturer	Medivators, Inc. a Cantel Medical Company	Smartdata Suzhou Co., Ltd	N/A
Product code	ODC	ODC	Identical
Classification	2	2	Identical
Regulation No	876.1500	876.1500	Identical
Regulation Name	Endoscope and accessories	Endoscope and accessories	Identical
Supplied Sterile	Sterile of the Olympus® / Fujinon® Style and Pentax® Style	Non Sterile of the Olympus ® / Fujinon® Style and Pentax® Style	Similar
Compatibility	Olympus® / Fujinon® and Pentax ® Endoscopes	Olympus® / Fujinon® and Pentax ® Endoscopes	Identical
Intended Use	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 endoscopic procedure.	The Endorate™ Disposable biopsy valve 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.	Identical
Environment of Use	Hospital and or clinics	Hospital and or clinics	Identical
Single Use, Disposable	Yes	Yes	Identical
Material	Styrene-ethylene-butene-styrene block copolymer	Silicone	Similar
Manufacturing Method	Injection molded	Injection molded	Identical

Slit in the valve cap	1.7-2.0mm	1.7-2.0mm	Identical
Removable Cap with Slit for Device Passage	Yes	Yes	Identical
Packaging	Suction, Air/Water, biopsy valves are housed in a single tray and packaged in a sealed pouch. Biopsy valve is also sold individually packaged in a sealed pouch.	Suction, Air/Water, biopsy valves are housed in a single tray and packaged in a sealed pouch. Non Sterile Biopsy valve is also sold individually packaged in a sealed pouch. Biopsy valve is either in blue or black depending on the availability.	Similar
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 was performed on Smartdata samples from initial production lots, including sterilization.

9.1. Disposable Suction Valve

9.1.1 Scope Compatibility
9.1.2 Valve Depression Force
9.1.3 Leak Test

9.2. Disposable Air/Water Valve

9.2.1 Scope Compatibility
9.2.2 Valve Depression Force
9.2.3 Air Ventilation and Insufflation
9.2.4 Water Flow Performance

9.3. Biopsy Valve

9.3.1 Scope Compatibility
9.3.2 Leak Testing
9.3.3 Squeegee Performance

A detailed record is attached as Appendix A in Section 18.

9.4 Sterilization

The Endorate™ valve set which consists of one suction valve, one air/water valve and one biopsy valve, is sold in sterile package, like the Medivators predicate device. The valve set 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 valve sets are below the maximum levels defined in ANSI/AAMI/ISO 10993-7:1995 *Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide sterilization residuals.* The Smartdata valve sets, and the predicate devices, are not labeled as pyrogen-free because they do not have any blood or cerebrospinal fluid contact. The Smartdata suction vale, air/water valve and biopsy valve are packaged in a paper/film pouch like other sterile products Smartdata currently manufactures.These pouches have been tested by Smartdata and shown to provide and maintain a sterile barrier for at least three (3) years.

9.5 Shelf Life

The Endorate™ valve set 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 valve sets are packaged in a paper/film pouch like other sterile products Smartdata currently manufactures. These pouches have been tested by Smartdata, including accelerated aging, seal strength, dye penetration and packaging persistence bacteria performance and shown to provide and maintain a sterile barrier for at least three (3) years.

10. Clinical Testing

Suction valve, air/water valve and biopsy valve 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 valve set which consists of suction valve, air/water valve and biopsy valve, have 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 valve set and the predicate devices.

The Smartdata valve set do not raise any new issues of safety and effectiveness.

From a clinical perspective and comparing design specifications, the Smartdata valve set and the predicate device are substantially equivalent.