SECTION 5: 510(k) SUMMARY STATEMENT

This 510(k) summary is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990, 21 CFR 807.92.

1. **General Information**

Date of Submission: August 25, 2017

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2. **Trade/Proprietary Name of Device:**

Common/Usual Name:	Endoscopic Accessories, Endoscopic Overtube, Endoscope Cap
Trade Name:	BAROnova Retrieval Kit BAROnova Endoscopic Overtube BAROnova Endoscope Cap
Regulation Number	876.1500
Regulation Description:	Endoscope and accessories
Product Codes:	FED, OCX
Device Panel:	Gastroenterology/Urology
Device Classification:	Class II

3. **Legally Marketed Predicate Devices for Claimed Equivalence:**

Name: US Endoscopy Guardus® Overtube
510(k) #: K040836

Name: US Endoscopy Distal Attachment Cap
510(k) #: K140315

4. **Device Description**

The BAROnova Retrieval Kit includes the following products:

- BAROnova Overtube Set (Overtube with a mated Obturator and Seal Cap)
- Endoscope Cap Set (Endoscope Caps, Small and Large)
- Push Tube

- Endoscope Cap Sizing Guide

The BAROnova Overtube Set (BAROnova Overtube) consists of a non-sterile, polymer extrusion with a metallic coil reinforcement, atraumatic tip and handle, in addition to a mated Obturator made of flexible PVC with a tapered tip, and a flexible polymer seal cap. The BAROnova Endoscope Cap Set (BAROnova Endoscope Caps) consists of two non-sterile, plastic caps for use with standard endoscopes. The Endoscope Caps are provided in two sizes to accommodate a range of standard endoscope sizes. The Push Tube (Class I, regulated under 876.4730 – Manual Gastroenterology-Urology Surgical Instrument and Accessories) and the Endoscope Cap Sizing Guide (Class I, regulated under 876.1500 – Endoscope and Accessories), are optional accessories included in the Retrieval Kit for use with the BAROnova Overtube and BAROnova Endoscope Caps respectively. The Push Tube is a non-sterile, plastic probe with a handle, which may be used to facilitate removal of foreign objects through the BAROnova Overtube. The Endoscope Sizing Cap Guide is an optional accessory for the BAROnova Endoscope Caps to assist the user in selecting the correct size Cap.

5. Indications for Use Statement

The Indications for Use for the products included within the Retrieval Kit are as below:

The disposable Overtube is a device used in conjunction with an endoscope for foreign body removal or endoscopic procedures requiring multiple insertions of the endoscope into the upper gastrointestinal tract.

The Endoscope Caps are intended to keep suitable endoscopic view field during endoscopic procedures.

6. Substantial Equivalence Comparison

Indications for Use

The BAROnova Overtube has the same indications for use as the predicate Guardus Overtube therefore the BAROnova device meets the standard of substantial equivalence.

Substantial equivalence for the BAROnova Endoscope Caps is supported by the predicate US Endoscopy Distal Attachment Cap, which includes the same Indication for Use statement. The BAROnova device is indicated to keep a suitable endoscopic view field during endoscopic procedures, whereas the predicate device is indicated both to keep a suitable endoscopic view field and for mucosal resection during endoscopic procedures. The indication for use for the BAROnova Endoscope Caps is within the indication for use for the predicate device and therefore the BAROnova device meets the standard of substantial equivalence.

Technological Characteristics
Aside from minor differences in dimensions and the inclusion of an integrated PTFE tip, the BAROnova Overtube has the same material and technological characteristics as the predicate Guardus Overtube. Dimensional, mechanical, biocompatibility, and preclinical simulated use data confirmed that the BAROnova Overtube performs as intended and that no new issues of safety and effectiveness are introduced.

Key technological characteristics of the BAROnova Endoscope Caps are similar to the predicate device. The BAROnova Endoscope Caps are dimensionally similar to the predicate US Endoscopy Distal Attachment Cap. The predicate device is made entirely of silicone whereas the distal portion (tissue contacting portion) of the BAROnova device is made of a polycarbonate. This difference is not significant as these two materials are performing the same intended function. The predicate device is provided sterile, due to its indication for mucosal resection. The BAROnova device is intended for keeping a suitable endoscopic field of view, which does not require a sterile device. Dimensional, mechanical, biocompatibility, and preclinical simulated use data confirmed that the BAROnova Endoscope Caps perform as intended and that no new issues of safety and effectiveness are introduced.

7. Summary of Performance Data (Non-clinical testing)

Non-clinical testing of the subject devices for structural and functional use has been performed, including dimensional, mechanical strength, simulated use, and biocompatibility. The subject devices were found to meet all requirements.

8. Conclusion

Substantial equivalence of the BAROnova Retrieval Kit is supported by a comparison of the intended use, indications for use, design and materials with the Guardus Overtube (K040836) and by a comparison of the intended use, indications for use, design and materials to the US Endoscopy Distal Attachment Cap (K140315), as well as acceptable results from preclinical, mechanical and biocompatibility tests.