

**COMEG**

Endoscopy

K 970764

P172

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**SUMMARY OF SAFETY AND EFFECTIVENESS FOR RESECTOSCOPE ACCESSORIES**

§807.92 (a)(1)

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§807.92 (a)(2)

Trade Name: COMEG Endoscopy Resectoscope Accessories

Common Name: Endoscope and accessories

Classification Name: Endoscope and accessories (21 CFR §876.1500)  
Urethral dilator (21 CFR §876.5520)

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§807.92 (a)(3)

Legally Marketed Substantially Equivalent Device: Karl Storz resectoscope accessories and Circon ACMI Sheaths

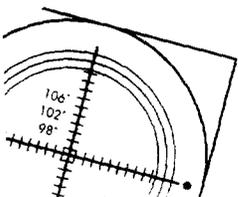
§807.92 (a)(4)

Description of Device: The COMEG Endoscopy devices that we intend to market include the following resectoscope accessories (Tier 1 devices): sheaths; obturators; cystoscope diagnostic adapters; dilator, urethral meatus; urological syringe and evacuator with adaptor; cystoscope (single action) scissors; and, luer lock connectors.

Resectoscope accessories are described in endoscope and accessories 21 CFR §876.1500 and dilators are described in urethral dilator 21 CFR §876.5520. The materials used to fabricate these devices include stainless steel, brass chrome plated, plastic (polyvinylchloride (PVC) and Tecapeek), PTFE, aluminum oxide, and silicone. The stainless steel of which these devices are fabricated is ASTM type 304 which meets the ASTM specification F899-84 Standards for Stainless Steel Billet, Bar and Wire for Surgical Instruments and is biocompatible with human tissue.

These devices can be reused and instructions for cleaning and sterilization will be provided.

§807.92 (a)(5)



Intended Use:

**Continuous-Flow Inner and Outer Sheaths** The intended use for the continuous-flow inner and outer sheaths is in urological procedures to endoscopically examine and allow access to the urethra and bladder and also provide simultaneous suction and irrigation for the resectoscope. The surgeon performs the procedure through the urethra. The sheaths are devices that allow for a less traumatic passage for cystoscopes, resectoscopes, and various instrumentation.

**2 Fixed Stopcock and 2-Way-Tap Outer Sheaths** The intended use for these devices is in urological procedures to endoscopically examine and allow access to the urethra and bladder. The surgeon performs the examination through the urethra. The sheaths are devices that allow for a less traumatic passage for cystoscopes and various instruments and also allow for simultaneous suction and irrigation.

**Obturator:** The intended use for the obturators is in urological procedures to endoscopically examine and allow access to the urethra and bladder. The obturator is inserted into the sheath and its blunt end protrudes from the distal end. It protects the tissue when the sheath is entered into the area under examination.

**Cystoscope Diagnostic Adapters** The intended use for the cystoscope diagnostic adapter is in urological procedures to bridge the cystoscope to the cystoscope sheath. In versions with operating channels, it also provides passage for instruments.

**Dilator, Urethral Meatus:** The intended use for the dilator is in urological procedures. It is inserted into the urethra and is intended to dilate the penis for insertion of a catheter or instrumentation.

**Urological Syringe and Evacuator with Adapter** The intended use for the urological syringe and evacuator with adapter is in urological procedures. The syringe is connected directly to the sheath and is used for manual suction and irrigation of the bladder. The evacuator is used to remove loose debris (tissue) from the bladder. It is also connected directly to the sheath.

**Single Action scissors** The intended use for the single action scissors is in urological and gastroenterological procedures to endoscopically cut tissue and/or sutures.

**Luer Lock Connectors:** The intended use for the luer lock connectors is in urological procedures. The luer is connected directly to the sheath suction and irrigation port and is used to connect catheters and suction and irrigation tubes to sheaths. They provide an adaption, extension, or stopcock.

§807.92 (a)(6)

Comparison of Technical Characteristics:

The subject devices are similar to devices marketed by Karl Storz and Circon ACMI. The predicate device for the "Quick-Connection" feature is the Circon ACMI inner and outer sheaths. The intended uses are the same for the subject devices and the competitors' products. The materials used to fabricate both the COMEG and the Karl Storz devices and the operational principles and mode of action are similar as well.