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SECTION II
510k Summary of Safety and Effectiveness

SAFETY AND EFFECTIVENESS
U.S.E. IRRIGATION/ASPIRATION POLYPECTOMY SNARES

The Summary of Safety and Effectiveness on the endoscopic procedure for removal of polyps and the polypectomy snare used reflects data available and present at the time the summary was prepared, but, caution should be exercised in interpreting the data. The results of future studies may require alteration for the conclusions or recommendations set forth.

Procedure/Product Overview

Polypectomy is a procedure whereby a polyp is removed from the gastrointestinal tract. A polypectomy snare is an instrument which enables the physician to grasp the polyp, transmit electrical current and transect the polyp.

The polypectomy snare is introduced through an endoscope and the snare wire is placed around the polyp. The snare wire is closed while simultaneously transmitting electrocautery to excise the polyp. Polypectomy snares have been clinically used for more than 20 years. Some Endoscope models have irrigation and suction capabilities that are commonly used during polypectomy procedures. The irrigation/aspiration polypectomy snare incorporates these capabilities into one device.

Contraindications for Polypectomy

Polypectomy via flexible endoscopy is contraindicated in the following cases:

- 1) If the polyp is too large to safely remove via flexible endoscopy.
- 2) If the depth of the polyp and the thickness of the wall and the level of penetration of thermal energy can not be determined.
- 3) Coagulopathy.
- 4) Poor bowel preparation.
- 5) Uncooperative patient.
- 6) Any contraindication to performing a colonoscopy.

The physician will determine patient's appropriateness for the procedure.

Manufacturing Overview

U.S.E. designs, manufactures and tests the product to performance specifications based on predicate and/or substantially equivalent devices.

U.S.E. manufacturing processes and procedures are based on good manufacturing practices. Quality assurance methods and procedures based on MIL-STD-9858 are utilized to assure conformance to design specifications.

Materials used in the manufacturing process are certified to standards appropriate for their use.

Sterility Testing

This product is sterilized using ETO sterilization method.

Bibliography

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