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SECTION II
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
REPLACEMENT GASTROSTOMY TUBE

The Summary of Safety and Effectiveness on percutaneous endoscopic gastrostomy and the Replacement Gastrostomy Tube used reflects data available and presented at the time the submission was prepared, but, caution should be exercised in interpreting the data. The results of future studies may require alterations of the conclusions or recommendations set forth.

Procedure/Product Overview

Percutaneous endoscopic gastrostomy (PEG) has become the method of choice for patients, both adults and children, unable to take nutrition through normal means, yet, have a functional gastrointestinal tract. Percutaneous endoscopic gastrostomy is a less invasive and traumatic method of placement than a surgical procedure.

The placement of PEGs, via endoscopy, has been clinically acceptable for more than 10 years. Several manufacturers provide PEG units to the market. The Gastrostomy tube is replaced with a Replacement Gastrostomy Tube for such things as indications of a blocked feeding tube, patient comfort and esthetics, and the need for long-term nutritional support.

Contraindications For Utilizing a Replacement Gastrostomy Tube and Percutaneous Endoscopic Gastrostomy

(1) Patients with massive ascites, sepsis, esophageal or gastric obstructions, esophageal or gastric varices and morbid obesity.
(2) Individuals who do not have a well established gastrostomy tract.
(3) If the patient is combative and can not be sedated.
(4) If the patient is bleeding.
(5) If the patient has signs of infection or irritation of stoma tissue.
(6) If the patient has evidence of granulation tissue at stoma site.
(7) A patient who does not have a well established gastrostomy tract.
(8) Evidence of granulation tissue, infection or irritation should be addressed medically prior to insertion of this device.
(9) Other contraindications as determined by physician.

Manufacturing Overview

U.S.E. 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

The Replacement Gastrostomy Tube will be sterilized using ETO. Sterilization parameters are on file with U.S. Endoscopy Group, Inc.

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