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SECTION II  
SUMMARY AND CERTIFICATION

**SAFETY AND EFFECTIVENESS**  
**P.E.G. PATIENT CARE KIT**

The Summary of Safety and Effectiveness on percutaneous endoscopic gastrostomy patient care kit 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 less traumatic method of placement than a surgical procedure.

The placement of PEGs, via endoscopy, has been clinical acceptable for more than 10 years. Several manufacturers provide PEG units to the market.

A U.S.E. PATIENT CARE KIT includes all necessary products for maintenance of the Pull or Guidewire P.E.G. (eg. feeding adapter, and accessory products - manual, cleaning brush, antibiotic ointment, etc...)

Contraindications For Utilizing a PEG

The following are contraindications for percutaneous endoscopic gastrostomy.

- (1) Patients with massive ascites, sepsis, esophageal or gastric obstructions, esophageal or gastric varices and morbid obesity.
- (2) If the patient's stomach can not be transluminated.
- (3) If the patient is combative and can not be sedated.

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.

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