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SECTION II
510(K) Summary of Safety & Effectiveness

The Summary of Safety and Effectiveness for the Papillotome 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

The Papillotome is intended for use in endoscopic papillotomy and sphincterotomy.

Contraindications for Papillotomy and Sphincterotomy Procedure

- . Coagulopathy
- . Acute pancreatitis (relative)
- . Allergy to contrast medium (relative)
- . Long stricture of the distal common bile duct
- . Presence of an extremely large stone
- . Inability to properly position sphinctertome
- . Other contraindications as determined by physician

Complications that May Occur

- . Bleeding
- . Perforation and impaction of stone or basket may occur as immediate complications
- . Torrential and late bleeding are rare
- . The occurrence of pancreatitis

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 Testing

The Papillotome is sterilized using EtO.

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Bibliography

- Hardick, Marcia and Beck, Marjorie (Editors), Manual of Gastrointestinal Procedures, (2nd Edition). New York: Society of Gastroenterology Nurses and Associates, Inc., 1989.
- Ravenscroft, M.M. and Swan, C.H.J. Gastrointestinal Endoscopy and Related Procedures. Baltimore: Williams & Wilkins, 1984.
- Berci, George Endoscopy. New York: Appleton-Century-Crofts, 1976.