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SECTION II
510(k) Summary of SAFETY AND EFFECTIVENESS
U.S.E. ENDOSCOPIC RETRIEVAL DEVICES (all versions) SUMMARY

The Summary of Safety and Effectiveness on the endoscopic procedure for retrieval of foreign bodies, tissue or polyps, stones or calculi 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 alterations of the conclusions or recommendations set forth.

Procedure/Product Overview

Endoscopic Retrieval is a procedure whereby a foreign body, polyp or tissue, stone or calculi is removed from the gastrointestinal tract or biliary tract. A retrieval device is an instrument which enables the physician to grasp and retrieve the object via endoscopic methods.

The retrieval basket is introduced through an endoscope and the basket is placed around the object. Retrieval baskets have been clinically used for more than 20 years.

Contraindications for retrieval of foreign body, tissue or polyp, stones or calculi

Retrieval via flexible endoscopy is contraindicated in the following cases:

1) If the risk or removal of the object is greater than the endoscopic procedure.
2) Uncooperative patient
3) Any contraindication to performing endoscopy
4) Known or suspected perforated viscus
5) Presence of large stones in biliary tract and other associated contraindications for therapeutic biliary procedures.

The physician will determine patient's appropriateness for 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

The Endoscopic Retrieval Devices will be sterilized using ETO gas and the methods will conform to AAMI standards for sterilization of medical devices.

Bibliography

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Berci, George Endoscopy. New York: Appleton-Century-Crofts, 1976.