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SUMMARY OF SAFETY AND EFFECTIVENESS
FlexMedics Corporation, FlexFinder® Guidewire

A. General Provisions

Submitter's Name: FlexMedics Corporation
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Classification Name: Gastrointestinal guidewire (Endoscope) 21 CFR
Part 876.1500 and (Electrosurgical) 21 CFR Part
876.4300.

Common or Usual Name: Guidewire

Proprietary Name: FlexFinder® guidewire

B. Name of Predicate Devices

Wilson-Cook Medical, Inc.	Protector Plus Guidewire	K910597
Boston Scientific Corporation	Zebra Guidewire	K931650
FlexMedics Corporation, Inc.	FlexFinder Guidewire	K942074

C. Device Description

The FlexFinder® Guidewire is available in a nominal diameter of 0.035" with marked and unmarked models encompassing lengths between 260 - 450 cm. The guidewire is constructed of a Nitinol, kink resistant core wire encapsulated in a PTFE coating. The core wire is tapered to provide flexibility of the distal tip. The guidewire is provided in two shaft flexibility's; regular shaft and stiff shaft. The guidewire will be available in both ink marked and unmarked models of each of the shaft flexibility's. For the marked models, the distal portion of the guidewire is marked visually with ink bands to allow for endoscopic detection of wire movement during a clinical procedure.

The encapsulated guidewire enables it to be used with wire guided electrosurgical devices providing insulation from the electrosurgical current during a procedure. The insulation meets the AAMI standard for High frequency Therapeutic devices(HF 18) which describes testing for reliability, safety, and effectiveness.

The guidewires are packaged, sterilized, and labeled and intended for one procedure use only(disposable).

D. Intended Use

The FlexFinder® Guidewire is designed to be used to guide and exchange endoscopic accessories and electrosurgical devices for biliary procedures. The FlexFinder® Guidewire is indicated for selective cannulation of the biliary ducts, including but not limited to the common bile, cystic, pancreatic, and right and left hepatic ducts.

E. Summary of Technological Characteristics

The FlexFinder® Guidewire uses common biocompatible materials which are identical to those of currently marketed Gastrointestinal guidewires manufactured by FlexMedics Corporation in K942074, Boston Scientific Corporation in K931650, Wilson-Cook Medical, Inc. in K910497.

F. Non-Clinical Test Summary

The guidewires have been verified as meeting specifications for electrosurgical devices providing insulation from the electrosurgical current; material integrity; dimensions; and, material biocompatibility. The results of functional testing were analyzed against product specifications and currently marketed devices. The test results demonstrate that the product meets requirements and is acceptable for its intended use.