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K961897

P1072

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK BILIARY INTRODUCER with ASPIRATION BIOPSY NEEDLE

J. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:

Wilson-Cook Medical Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105

Device Description:

The Wilson-Cook Biliary Introducer with Aspiration Biopsy Needle consists of double lumen tubing, a 22 gauge needle and proximal hubs. This device is designed for insertion through the accessory channel of an endoscope, and may be placed over a previously positioned .035" wire guide. The catheter is advanced through the accessory channel, positioning the side ramp below the biopsy site. The needle is advanced and cells are aspirated using a 20 cc syringe. After cell collection, if desired, the needle can be removed, leaving the inner catheter in place for the introduction of other conventional biopsy instruments.

Trade Name: Wilson-Cook Biliary Introducer with Aspiration Biopsy Needle

Common/Usual Name: Aspiration Biopsy Needle

Classification Name: Set, Biopsy Needle and Needle, Gastro-Urology 78FCG

Classification: FDA has classified similar devices as Class II, per 21 CFR § 876.1075. This device falls within the purview of the Gastroenterology and Urology Devices Panel.

Performance Standards: To the best of our knowledge, performance standards for this device do not exist.

Sterility: Validated EO cycle, following the AAMI Overkill Method to SAL 10⁻⁶.

Intended Use: The Wilson-Cook Biliary Introducer with Aspiration Biopsy Needle is used for aspiration biopsy in the biliary system, and if desired for the introduction of other biopsy instruments.

Predicate Device:

PREDICATE DEVICE	MANUFACTURER	DOCUMENT CONTROL NUMBER
Wilson-Cook Biliary and Gastric Aspiration Needle	Wilson-Cook Medical Inc.	K895900

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK BILIARY INTRODUCER with ASPIRATION BIOPSY NEEDLE

J. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

DEVICE CHARACTERISTIC	WILSON-COOK BILIARY INTRODUCER with ASPIRATION BIOPSY NEEDLE [Subject of 510(K)]	WILSON-COOK BILIARY & GASTRIC ASPIRATION NEEDLES (K895900)
Intended Use	Needle aspiration biopsy in the biliary system and if desired introduction of biopsy instruments.	Needle aspiration biopsy in the biliary system.
Introducer Catheter/Sheath	Polytetrafluoroethylene	Polytetrafluoroethylene
Needle	304 Stainless Steel	304 Stainless Steel
French Size	Introduction Catheter: 10 French Introduction Catheter Tip: 6 French Inner Catheter (Needle): 5 French	7 French
Length	200 cm	190 cm
Needle Gauge	22 GA	22 GA
Needle Extension	7 mm	7.5 mm
Number of Lumens	2	1
Sterility	Sterile, disposable	Sterile, disposable

Testing: Biocompatibility has been established for the patient contacting materials through a history of use in other similar medical devices.

The Wilson-Cook Biliary Introducer with Aspiration Biopsy Needle has been subjected to our internal standard operating procedures for product qualification and process validation. Samples were subjected to visual, dimensional and functional analysis. All samples were deemed acceptable, in that test specifications were met.