K182253

510(k) SUMMARY

FUJIFILM Video Bronchoscopes EB-530H, EB-530S, and EB-530T

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Submitter's Information:

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Identification of the Proposed Device:

Proprietary/Trade Name:	FUJIFILM Video Bronchoscopes EB-530H, EB-530S, and EB-530T
Common Name:	Bronchoscope
Device Class:	Class II
Review Panel:	Ear, Nose & Throat
Classification:	Bronchoscope and accessories, 21 C.F.R. § 874.4680
Product Code:	EOQ

Predicate Device:

FUJIFILM Video Bronchoscopes EB-530H, EB-530S, and EB-530T (K122535)

Intended Use / Indications for Use:

EB-530H, EB-530S, and EB-530T are intended for the observation, diagnosis, and endoscopic treatment of the trachea and bronchial tree.

Device Description:

FUJIFILM Video Bronchoscopes EB-530H, EB-530S, and EB-530T are comprised of three general sections: a control portion, an insertion portion and an umbilicus. The control portion controls the angulation of the endoscope. This portion also controls the flexibility of the distal end in the endoscope. The insertion portion contains glass fiber bundles, several channels and a complementary Charge-Coupled Device (CCD) image sensor in its distal end. The channels in the insertion portion assist in delivering air/suction as well as endoscope accessories, such as forceps. The glass fiber bundles allow light to travel through the endoscope and emit light from the tip of the insertion portion to illuminate the body cavity. This provides enough light to the CCD image sensor to capture an image and display it on

the monitor. The umbilicus consists of electronic components needed to operate the endoscope when plugged in to the video processor and the light source. The endoscope is used in combination with FUJIFILM's video processors, light sources and peripheral devices such as monitor, printer, foot switch, and cart.

Technological Characteristics:

The proposed devices EB-530H, EB-530S, and EB-530T differ from the predicate devices in the following minor modifications:

- Compatibility with Video Processor VP-7000 and Light Source BL-7000 (K163675).
- Compliance to IEC60601-1 edition 3.1 to support compatibility with VP-7000 and BL-7000.
- Expansion of transport and storage conditions to a temperature range of -20°C to 60°C and a humidity range of 10 to 85% RH.
- Use of a new epoxy resin in the manufacturing process. Both the new and original epoxy resins can be used for repair.

Performance Data:

Electrical safety of the proposed devices were evaluated using the following standards: ANSI/AAMI ES 60601-1:2012, IEC 60601-1-2:2007, IEC 60601-1-6:2013, and IEC 60601-2-18:2009.

The proposed devices EB-530H, EB-530S, and EB-530T were adopted into biocompatibility testing conducted on the predicate devices EB-530H, EB-530S, and EB-530T using the following consensus standards: ISO 10993-1:2009, ISO 10993-5:2009, and ISO 10993-10:2010.

Fujifilm conducted the following performance testing on the proposed devices EB-530H, EB-530S, and EB-530T to ensure that the modified devices perform equivalently to the predicate devices:

- Field of view
- Bending capability
- Suction rate
- Working length
- Forceps channel diameter
- Viewing direction
- Resolution
- LG output

In all cases, the devices met the pre-defined acceptance criteria for the test.

Substantial Equivalence:

The company's EB-530H, EB-530S, and EB-530T have the same intended use and indications for use as the previously cleared predicates EB-530H, EB-530S, and EB-530T (K122535). In addition, the proposed devices have similar technological characteristics and principles of operation as the predicates. The minor differences between the proposed devices and their predicate devices do not raise new or additional questions of safety or effectiveness of the proposed devices. Thus, the proposed devices EB-530H, EB-530S, and EB-530T are substantially equivalent to their predicate devices.

Conclusions:

The modified EB-530H, EB-530S, and EB-530T are substantially equivalent to the predicate EB-530H, EB-530S, and EB-530T and conform to applicable medical device safety and performance standards.