K121035

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JUN - 4 2012

510(k) Summary

Date: June 4, 2012

Submitter's Information:

FUJIFILM Medical Systems U.S.A., Inc.
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FDA Establishment Registration Number: 2431293

Contact Person:

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Identification of the Proposed Device:

Proprietary/Trade Name: Fujinon/Fujifilm Ultrasonic Endoscope EB-530US
Common Name: Ultrasonic Bronchoscope
Device Class: Class 2
Review Panel: Ear Nose & Throat
Classification Information:

Classification Name	CFR Section	Product Codes
Bronchoscope (flexible or rigid) and accessories	21 CFR 874.4680	EOQ
Diagnostic Ultrasonic Transducer	21 CFR 892.1570	ITX

I. INDICATIONS FOR USE

The Fujinon/Fujifilm Ultrasonic Endoscope EB-530US is intended for the observation, diagnosis and endoscopic treatment of the trachea, bronchial tree and surrounding organs using ultrasonic images. It is used with Fujinon/Fujifilm ultrasonic processor, video processor, light source, other peripheral equipment and endoscopic accessories. It is not intended for use on children and infants.

II. DEVICE DESCRIPTION

Fujinon/Fujifilm Ultrasonic Endoscope EB-530US is intended for the observation, diagnosis and endoscopic treatment of the trachea, bronchial tree and surrounding organs using ultrasonic images. EB-530US is used in combination with the Fujinon/Fujifilm's ultrasonic processor, video endoscope processor, light source, monitor, cart, foot switch, endoscope accessories and other peripheral devices. When used with a Fujinon/Fujifilm's ultrasonic processor, EB-530US emits ultrasound wave and scans the reflected signals to provide ultrasonic images. For ultrasound procedure, EB-530US can be used with a

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single-patient-use balloon. A balloon inflated with sterile water for an ultrasonic endoscope eliminates air between the ultrasonic transducer and target tissue so that the ultrasound wave can travel with little interference. Additionally EB-530US supports ultrasound guided needle aspiration.

III. SUMMARY OF STUDIES

Fujinon/Fujifilm Ultrasonic Endoscope EB-530US conforms to the following internal and international IEC testing requirements in addition to the applicable quality system regulations:

IEC 60601-1	Medical electrical equipment - Part 1: General requirements for safety
IEC60601-1-1	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
IEC60601-1-2	Medical electrical equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and tests
IEC60601-2-18	Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment
IEC 60601-2-37	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
ISO10993-1	Biological evaluation of medical devices

The balloon, B20BU for the Fujinon/Fujifilm Ultrasonic Endoscope EB-530US conform to the applicable internal and international IEC testing requirements for Sterility.

The reprocessing instructions were validated.

No clinical testing was conducted.

IV. SUBSTANTIAL EQUIVALENCE

Fujinon/Fujifilm Ultrasonic Endoscope EB-530US is substantially equivalent to the following device:

Legally Marketed Device(s)	510(k) #
EVIS EXERA Ultrasonic Bronchofibervideoscope OLYMPUS BF type UC160F-OL8	K042140

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Comparison is outlined in the table below.

		Legally Marketed Device K042140	Proposed Device Model EB-530US
Viewing direction		35 degree forward oblique	10 degree forward oblique
Observation range		2-50 mm	3-100 mm
Field of view		80 degree	120 degree
Distal end diameter		6.9 mm	6.7 mm
Flexible portion diameter		6.2 mm	6.3 mm
Bending capability	Up	120 degree	130 degree
	Down	90 degree	90 degree
Forceps channel diameter		2.0 mm	2.0 mm
Working length		600 mm	610 mm
Total length		890mm	880 mm
Scanning method		Electrical curved linear array	Electrical curved linear array
Scanning range		50 degree	60 degree (with SU-7000) 65 degree (with SU-8000)
Ultrasonic operating frequency		7.5 MHz	5 MHz, 7.5 MHz, 10 MHz, 12 MHz

All patient contact materials used in the proposed EB-530US remain the same as the previously-cleared Fujinon/Fujifilm endoscopes.

V. CONCLUSION

Fujinon/Fujifilm Ultrasonic Endoscope EB-530US is substantially equivalent to the legally marketed device and conforms to applicable medical device safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FUJIFILM Medical Systems U.S.A., Inc.
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

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Re: K121035
Trade/Device Name: Fujinon/Fujifilm Ultrasonic Endoscope EB-530US
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOQ, ITX
Dated: April 4, 2012
Received: April 5, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jessia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): _____

Device Name: Fujinon/Fujifilm Ultrasonic Endoscope EB-530US
[To be used with Fujinon/Fujifilm Ultrasonic Processor (SU-7000/SU-8000)]

Indications for Use:

The Fujinon/Fujifilm Ultrasonic Endoscope EB-530US is intended for the observation, diagnosis and endoscopic treatment of the trachea, bronchial tree and surrounding organs using ultrasonic images. It is used with Fujinon/Fujifilm ultrasonic processor, video processor, light source, other peripheral equipment and endoscopic accessories. It is not intended for use on children and infants.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K121035

Prescription Use X
(Per 21 CFR 801.109)

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Diagnostic Ultrasound Indications For Use

510(k) Number (If Known): _____

System Name: Fujinon/Fujifilm Ultrasonic Processor (SU-7000/SU-8000)

Transducer: Ultrasonic Endoscope EB-530US

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific	B	M	PWD	CWD	Color Doppler	Combined[1]	Other
Ophthalmic	Ophthalmic							
General Application	Fetal							
	Abdominal							
	Intra-operative							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Tran-esoph. (non-Card.)	N	N	N		N	N[1]	
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)[2]	N	N	N		N	N[1]	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Tran-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P = previously cleared by FDA; E = added under this appendix

[1] Combined modes includes B+M, B+CD, B+PWD, B+CD+PWD modes

[2] Other (Specify): Trachea, bronchial tree and surrounding organs

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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X

Prescription Use _____

(Per 21 CFR 801.109)