FUJIFILM

510(k) Summary

AUG 13 2012

Date: December 16, 2011

Submitter's Information:

Fujinon Inc.
10 High Point Drive
Wayne, NJ 07470 USA
FDA Establishment Registration Number: 2431293

Contact Person:

Name: Gina Walljasper
Title: Director, Quality and Regulatory Compliance
Telephone: (973) 633-5600 Ext. 484
Facsimile: (973) 633-8818
E-Mail: gwalljasper@fujifilm.com

Identification of the Proposed Device:

Proprietary/Trade Name: Fujinon/Fujifilm Ultrasonic endoscope, EG-530UR2 and EG-530UT2
Common Name: Ultrasonic Endoscope
Device Class: Class 2
Review Panel: Gastroenterology/Urology
Classification Information:

Classification Name	CFR Section	Product Codes
Gastroscope and accessories, flexible/rigid	21 CFR 876.1500	FDS
Diagnostic Ultrasonic Transducer	21 CFR 892.1570	ITX

I. INDICATIONS FOR USE

Fujinon/Fujifilm Ultrasonic Endoscopes, EG-530UR2 and EG-530UT2, are intended to provide ultrasonic images of submucosal and peripheral organs of the upper gastrointestinal tract for observation, diagnosis and endoscopic treatment. The product is intended to be used with a Fujinon/Fujifilm ultrasonic processor. This product is not intended for use on children and infants.

II. DEVICE DESCRIPTION

Fujinon/Fujifilm Ultrasonic Endoscopes EG-530UR2 and EG-530UT2 are modified versions of our previously-cleared EG-530UR and EG-530UT via K063847. The modified models are intended to provide ultrasonic images of submucosal and peripheral organs of the upper gastrointestinal tract for observation, diagnosis and endoscopic treatment when used with a Fujinon/Fujifilm's ultrasonic processor, which remains the same as K063847.

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The modified models are used in combination with a 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, EG-530UR2 and EG-530UT2 model emits ultrasound wave and scans the reflected signals to provide ultrasonic images.

Detailed information on the modifications for the proposed endoscopes EG-530UR2 and EG-530UT2 are provided in the submission.

III. SUMMARY OF STUDIES

Fujinon/Fujifilm Ultrasonic endoscope EG-530UR2 and EG-530UT2 were evaluated in accordance with following safety and performance 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 the basic safety and essential performance - 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	Biological evaluation of medical devices

The reprocessing instructions were updated and validated using a third party lab. No clinical test was conducted.

IV. SUBSTANTIAL EQUIVALENCE

Fujinon/Fujifilm Ultrasonic endoscope EG-530UR2 and EG-530UT2 are substantially equivalent to the following device(s):

Legally Marketed Device(s)	510(k) #
Fujinon Ultrasonic Endoscopes & Processor (EG-530UR, EG-530UT and SU-7000)	K063847
Fujinon Ultrasonic Processor SU-8000	K111243

See Section 12 Comparison Matrix for detailed comparison.

V. CONCLUSION

Fujinon/Fujifilm Ultrasonic endoscope EG-530UR2 and EG-530UT2 are substantially equivalent to the legally marketed devices and conforms to applicable medical device safety and performance standards.

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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

AUG 13 2012

FUJIFILM Medical System U.S.A., Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K120446
Trade/Device Name: Fujinon/Fujifilm Ultrasonic endoscope (EG-530UR2 and EG-530UT2) [to be used with Fujinon/Fujifilm ultrasonic processor (SU-7000/SU-8000)]
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDS, ITX
Dated: August 2, 2012
Received: August 3, 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,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (If Known): K120446

Device Name: Fujinon/Fujifilm Ultrasonic endoscope (EG-530UR2 and EG-530UT2) [to be used with Fujinon/Fujifilm ultrasonic processor (SU-7000/SU-8000)]

Indications for Use:

Fujinon/Fujifilm Ultrasonic Endoscopes, EG-530UR2 and EG-530UT2, are intended to provide ultrasonic images of submucosal and peripheral organs of the upper gastrointestinal tract for observation, diagnosis and endoscopic treatment. The product is intended to be used with a Fujinon/Fujifilm ultrasonic processor. This product 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DRGUS 13 August 2012

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120446

Diagnostic Ultrasound Indications For Use

510(k) Number (If Known): K120446

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

Transducer: Ultrasonic Endoscope (EG-530UR2)

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.)	P	P	P		P	P[1]	
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)[2]	P	P	P		P	P[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+PWD, B+CD+PWD modes

[2] Other includes gastro-intestinal tract and surrounding organs

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher DRGUS 13 AUGUST 2012

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120446

Diagnostic Ultrasound Indications For Use

510(k) Number (If Known): K120446

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

Transducer: Ultrasonic Endoscope (EG-530UT2)

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.)	P	P	P		P	P[1]	
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)[2]	P	P	P		P	P[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+PWD, B+CD+PWD modes

[2] Other includes gastro-intestinal tract and surrounding organs

13 August 2012

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120446