

JUN - 7 2004

510 (k) Summary

Date Prepared [21 CFR 807.92(a)(1)]

January 9, 2004

Submitter's Information [21 CFR 807.92(a)(1)]

Joseph M. Azary
C/o Fujinon Inc.
543 Long Hill Avenue
Shelton, CT. 06484

Azary Technologies has received authorization to submit this 510(k) on behalf of the sponsor Fujinon Inc. 10 High Point Drive, Wayne, NJ 07470, Establishment Registration# 2431293.

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

The device trade names are: Fujinon Double Balloon Enteroscopy System

Common Name: Enteroscope

Classification: Class II, 21 CFR 876.1500, FDA

Predicate Device [21 CFR 807.92(a)(3)]

- Fujinon Enteroscope EN-410WM – K993704

The subject device have the same indications for use, material composition, viewing direction, image size, bending, reprocessing/sterilization method, and working dimensions as the predicate. The subject device uses the same processor and peripherals as the predicate device.

The main differences between the subject device and predicate device are as follows:

- Minor differences with observation range, field of view, diameter, and length.
- Subject device includes an overtube, balloons, and a balloon pump.
- The subject device includes the G5 upgrade, which is characterized by the following minor differences:
 - The L-Port has been eliminated. The L-port functioned as a lens wash port . Doctors had the option to take a syringe to inject a fluid to use it as a high pressure wash for the lens. This function was eliminated because demand was low and it was rarely used by the surgeons.
 - The J-Port was repositioned. The J-Port is used as a jet water wash port. The J-Port was repositioned based on doctor feedback. The port was moved from the bottom part to the top (end) of the scope. There was also a desire to eliminate check valves to facilitate reprocessing and cleaning, as well as prevent clogging.

Fujinon Double Balloon Enteroscopy System

- A G5 forceps inlet port was modified. The new port is smaller and comes with a rubber cap. The smaller port and rubber cap help increase suction and reduce leakage.
- The jet wash line check valve was removed. Internal check valves were removed to eliminate the potential for clogging and to facilitate cleaning, disinfection, and sterilization. The valves are now external and removable.
- The suction and air/water cylinders and valves were upgraded. They were updated to accommodate the new valves. The function of the valves is the same.
- Addition of the FOV, which is the rubber forceps inlet valve cover. This helps create a watertight seal when the endoscope is used.
- Upgrade to CA-500 cleaning adaptor. The cleaning adaptor allows the scope to be connected to tubes for cleaning.

Description of the Device [21 CFR 807.92(a)(4)]

The small intestine is one of the most difficult organs to access in gastro-intestinal (GI) tract endoscopy. The Fujinon double balloon enteroscopy system facilitates diagnosis and treatment of the upper GI tract including the small intestine.

The Fujinon double balloon enteroscopy system utilizes specialized balloons and over-tube to ensure complete positioning of the enteroscope in the small intestine. The tip of the scope can be smoothly inserted to reach the area of diagnosis.

The Fujinon double balloon enteroscopy system includes the following:

- G5 endoscope / enteroscope (EN-450P5/20)
- Over-Tube (TS-12140)
- Balloon (BS-1)
- Balloon Pump Controller (PB-10)

The subject device is used with the Fujinon Series 400 processor, the same processor used with the predicate device.

The Fujinon double balloon enteroscopy system is used in conjunction with other peripherals specified in the Operation Manual such as:

- Light Source
- Processor
- Cart
- Data Keyboard
- Foot Switch
- Monitor
- Video Printer
- Camera and Hard Copy Unit
- VCR
- ElectroSurgical Instruments

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Fujinon Double Balloon Enteroscopy System

Specifications Chart:

EN-450P5/20

Viewing Direction	Forward
Observation Range	5~100mm
Field of view	120
Image size	130% (super)
Distal end diameter	8.5mm
Flexible portion diameter	8.5mm
Bending capability	See below
Up	180
Down	180
Left	160
Right	160
Forceps channel diameter	2.2mm
Working length	2000mm
Total length	2300mm

Lens diameter	2.1mm
# of pixels	411,988 pixels
Pixels per square mm	83,892
Pixel size (H x V)	.0032 x .003725
Active area of CCD (H x V)	2.458 x 1.840
Type of CCD chip	Interline color chip

Resolution: near	11.1 lines/mm (5mm)
Resolution: far	.63 lines/mm (100mm)
Magnification	18.46 (5mm) on 14"
Focal length	.95mm

Over-Tube Specifications

Outer Diameter	12.2 mm
Total Length	1,450 mm

Balloon Pump Controller with Remote Switch PB-10 Specifications

Set Pressure of Balloon	3.6 kpa – 7.6 kpa (5.6 kpa +/- 2 kpa)
Maximum flow rate of pump	170 ml/10 sec
Power Supply	120V / 230V
Dimensions	300 (W) x 200(H) x 300(D) mm
Weight	8.7 kg

The balloon is composed of natural rubber, which has been subjected to and passed biocompatibility testing. The overtube is composed of polyvinylpyrrolidone hydromer coating, which has been subjected to and passed biocompatibility testing.

Intended Use [21 CFR 807.92(a)(5)]

The device is intended for the Optical visualization of the upper gastrointestinal tract. This includes the esophagus, stomach, duodenum, and small bowel. It is intended for the observation, diagnosis, and endoscopic treatment.

Technological Characteristics [21 CFR 807.92(a)(6)]

Fujinon, Inc. believes that the subject device is substantially equivalent to the predicate device. The subject device have the same indications for use, material composition, viewing direction, image size, bending, re-processing/sterilization method, and working dimensions as the predicate. The subject device uses the same processor and peripherals as the predicate device.

The main technological difference is the use of the balloon and overtube as a way to facilitate diagnosis and treatment of the upper GI tract including the small intestine, as well as the minor changes associated with the G5 upgrade.

Performance Data [21 CFR 807.92(b)(1)]

The subject device has been subjected to and passed electrical safety, thermal, and EMC testing requirements. The materials in the endoscope are identical to the materials used in the predicate device. The balloon and overtube materials have been subjected to and passed biocompatibility testing.

Conclusion [21 CFR 807.92(b)(3)]

We believe the changes are minor and conclude that the subject devices are as safe and effective as the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2004

Fujinon, Inc.
c/o Mr. Joseph M. Azary
Azary Technologies LLC
543 Long Hill Avenue
SHELTON CT 06484

Re: K040048

Trade/Device Name: Fujinon Double Balloon Enteroscopy System
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Product Code: 78 FDA
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Product Code: 78 KNT
Regulatory Class: II
Dated: May 5, 2004
Received: May 7, 2004

Dear Mr. Azary:

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.

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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Fujinon Double Balloon Enteroscopy System

5 10(k) Number (if known): K 04 00 48

Device Name: Fujinon Inc. Double Balloon Enteroscopy System

Indications For Use: The device is intended for the Optical visualization of the upper gastrointestinal tract. This includes the esophagus, stomach, duodenum, and small bowel. It is intended for the observation, diagnosis, and endoscopic treatment.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

David A. Lyman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040048

Fujinon Inc.
Double Balloon Enteroscopy 510(k)
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