NOV 1 0 2004

510 (k) Summary

K041903

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

July 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 G5 Colonoscopes

Common Name: Colonoscope

Classification: Class II, 21 CFR 876.1500, FDF

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

- Fujinon EC-400HL – K944620
- Fujinon EC-200LR – K944759

The G5 changes were described and cleared by FDA in the 510(k) submission for the Fujinon Double Balloon Enteroscopy System – K040048.

This 510(k) captures some minor design changes that have occurred during the evolution of the product line resulting in the G5 family of scopes. Although the changes are believed to be minor, the 510(k) is being submitted to account for "design creep" and to ensure that FDA has the most current information concerning the Fujinon Colonoscopes.

The subject device have the **same** indications for use, composition of patient contact materials, viewing direction, image size, bending capacity, and reprocessing/sterilization method as the predicate. The subject devices use the same processors 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.
- 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.

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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.
- 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 Fujinon G5 Colonoscopes are medical endoscopes used for visualization of the lower digestive tract, specifically intended for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine.

The G5 colonoscopes include minor changes that improve the useability, ergonomics, and cleaning of the devices. The G5 scopes do not have an L-Port. 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.

A G5 forceps inlet port was modified. The new port is smaller and comes with a rubber cap. The new design helps 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.

The G5 colonoscopes also feature the 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.

The G5 colonoscopes are used with a processor (EPX-201 for EC-250HL5 and VP-402 for EC-450HL5), a monitor, hard copy unit, and a cart. Each colonoscope is packaged in a protective carrying case with lens

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cleaner, silicon oil, forceps valve, waterproof cap, S connector cap, protective cap, adapters, valves, and the Operation Manual.

The Fujinon G5 colonoscopes are 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

Specifications for EC-450HL5 and EC-250HL5

	EC-450HL5	EC-250HL5
Viewing Direction	Forward	Forward
Observation Range	3-100mm	7-100mm
Field of View	140 degrees	140 degrees
Image Size	Super Image	Super Image
Distal End Diameter	12.8mm	12.9mm
Flexible Portion Diameter	12.8mm	12.8mm
Bending Capacity UP	180 degrees	180 degrees
Bending Capacity DOWN	180 degrees	180 degrees
Bending Capacity LEFT	160 degrees	160 degrees
Bending Capacity RIGHT	160 degrees	160 degrees
Forceps Channel Diameter	3.8mm	3.8mm
Working Length	1690mm	1690mm
Total Length	1990mm	1990mm

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

The device is intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine.

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, composition of patient contact material, viewing direction, image size, bending, and reprocessing/sterilization method as the predicate. The subject devices use the same processors and peripherals as the predicate devices.

The main differences are the minor changes associated with the G5 upgrade. The G5 changes were previously cleared by FDA in the 510(k) submission for the Fujinon Double Balloon Enteroscopy System – K040048.

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

The subject device has been subjected to and passed EMC testing requirements. The patient contact materials in the colonoscopes are identical to the materials used in the predicate device.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 0 2004

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

Re: K041903
Trade/Device Name: Fujinon Inc. G5 Colonoscopes
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FDF
Dated: October 17, 2004
Received: October 19, 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 (Premarket Approval), it may be subject to such 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

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

Enclosure

510(k) Notification
Fujinon G5 Colonoscopes

510(k) Number (if known): K041903

Device Name: Fujinon Inc. G5 Colonoscopes

The device is intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041903