MAY 19 2005

K050907

510 (k) Summary

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

March 31, 2005

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)]

Trade Names: Fujinon G5 Bronchoscopes
Models: EB-470S, EB-250S, and EB-270P

Common Name: Bronchoscope
Classification: Class II, 21 CFR 874.4680, EOQ

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

- Fujinon EB-310S (K954707)

The G5 Technology has received FDA marketing clearance in the following 510(k) Premarket Notifications:

- K042076 Fujinon G5 Duodenoscopes
- K042043 Fujinon G5 Gastroscopes
- K041903 Fujinon G5 Colonoscopes

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.
- 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.
- 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.

A chart comparing the subject device to the predicate device can be found in Annex 8. Additional information regarding the predicate device can be found in Annex 4.

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

The Fujinon G5 Bronchoscopes are medical endoscopes used for the observation, diagnosis, and endoscopic treatment of the trachea and broncho.

- The G5 Bronchoscopes are offered in a 200 and 400 series. The EB-250S represents the G5 Bronchoscope 200 series and the EB-470S represents the G5 Bronchoscope 400 series.

The G5 Bronchoscopes 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 reduces 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 Bronchoscopes 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 Bronchoscopes are used with the same processors, monitors, hard copy units, and carts as the predicate devices. Each Duodenoscope is packaged in a protective carrying case with lens cleaner, silicon oil, forceps valve, waterproof cap, S connector cap, protective cap, adapters, valves, and the Operation Manual.

The Fujinon G5 Bronchoscopes 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 Chart:

	EB-250S	**EB-470S**	**EB-270P**
Viewing Direction	Forward	Forward	Forward
Observation Range	3-50mm	3-100mm	3-100mm
Field of view	120 degrees	120 degrees	120 degrees
Image size	Super Image	Super Image	Super Image
Distal end diameter	5.3 mm	4.9mm	3.8 mm
Flexible portion diameter	5.3 mm	4.9mm	3.5 mm
Bending capability			
Up	180 degrees	180 degrees	180 degrees
Down	130 degrees	130 degrees	130 degrees
Left	N/A	N/A	N/A
Right	N/A	N/A	N/A
Forceps channel diameter	2.0mm	2.0mm	1.2 mm
Working length	600mm	600mm	600mm
Total length	870mm	870mm	870mm
Processor	200 Series	400 Series	200 Series

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

The device is intended for the observation, diagnosis, and endoscopic treatment of the trachea and *bronchial tree.*

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 differences are 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.

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

MAY 19 2005

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

Re: K050907
Trade/Device Name: Fujinon G5 Bronchoscopes, Models EB-407S, EB-250S and EB-270P
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope and Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: March 31, 2005
Received: April 11, 2005

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 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 (301) 827-8910. 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 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/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5 10(k) Number (if known): K050907

Device Name: Fujinon Inc. G5 Bronchoscopes

Indications For Use: The device is intended for the observation, diagnosis, and endoscopic treatment of the trachea and *bronchial tree.*

(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)

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

510(k) Number k050907