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Submission Type: Special 510(k)

Date Prepared [21 CFR 807.92(a)(1)]: June 10, 2009

AUG 07 2009

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

This 510(k) is being submitted by Joseph Azary on behalf of Fujinon Inc.

Contact:
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Sponsor / U.S. Distributor:
Fujinon Inc.
10 High Point Drive
Wayne, NJ 07470
FDA Establishment Registration# 2431293.

Manufacturer:
FujiFilm Corporation
1-324 Uetake-Cho
Kita-Ku, Saitama-Shi
Saitama 331-9624, Japan
FDA Establishment Registration# 9610875

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

Device Trade Name: Fujinon Sterile Overtubes
Device Common, Usual, or Classification Names: Endoscope Accessories
Classification: Class II, 21 CFR 876.1500, FDS and KOG

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

Fujinon Overtubes included with Double Balloon Enteroscopy - K040048
Fujinon Overtubes included with EC-450BI5 – K090116

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

The Fujinon double balloon enteroscopy system (K040048) and EC-450BI5 (K090116) utilize specialized overtubes to ensure complete positioning of the enteroscope or colonoscope in the digestive tract and to ensure the tip of the scope can be smoothly inserted to reach the area of diagnosis.

The overtube (TS-12140) was included in the original 510(k) K040048 and the overtube (TS-13101) was included in 510(k) K090116 with the EC-450BI5.

This submission includes the following items:

Product	Product Name	Comments
TS-12140	Over Tube	Originally included in the K040048 as non-sterile.
TS-13140	Over Tube	
TS-13101	Over Tube	Including in K090016.

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

The sterile overtubes are intended to be used as accessories with the Fujinon Enteroscopes and Colonoscopes cleared for use with overtubes. The overtubes are used to assist with the movement of the scopes inside the upper or lower digestive tract.

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

Fujinon, Inc. believes that the subject device is substantially equivalent to the predicate device. The subject devices have the **same** indications for use, dimensions, and material composition as the predicate. The only difference is the subject devices are offered as sterile devices.

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

The subject device has been subjected to and passed biocompatibility requirements and the sterilization process has been validated per ISO standards.

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 device.

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

Fujinon, Inc.
% Mr. Joseph M. Azary
Senior Regulatory Consultant
Orchid Design
80 Shelton Technology Center
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AUG 07 2009

Re: K091773
Trade/Device Name: Fujinon Sterile Over Tubes
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: July 17, 2009
Received: July 22, 2009

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); 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091773

Device Name: Fujinon Sterile Over Tubes

Indications For Use:

The sterile overtubes are intended to be used as accessories with the Fujinon Double Balloon Enteroscopy system, which is used for the optical visualization of the gastrointestinal tract

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091773