3.1 Summary of Safety and Effectiveness

AUG 17 2005

Non-Confidential Summary of Safety and Effectiveness

Page 1 of 2

7-Jun-05

Fuji Systems Corporation
3-23-14, Hongo, Bunkyo-ku
Tokyo, Japan 113-0033

Tel – 011-81-3-5689-1913
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Official Contact: Yoshi Semba – Director, International Division

Proprietary or Trade Name: Silbroncho® tubes

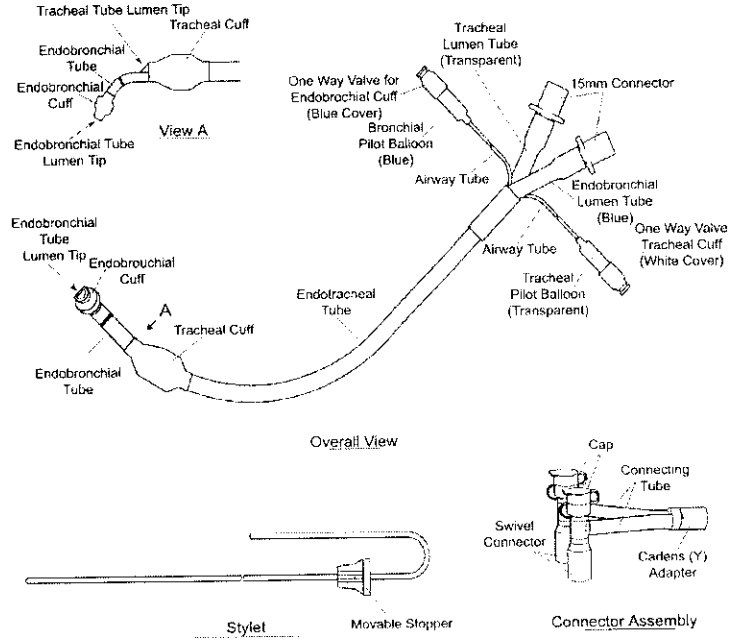
Common/Usual Name: Double lumen tube

Classification Name: Differential ventilation tracheal / bronchial tube with and without connectors

Predicate Devices: Mallinckrodt Broncho-Cath – K771219
Vitaid wire reinforced ET tube – K932647

Device Description:

The Silbroncho® double lumen tube is made of silicone and is available in sizes 33 to 39 French. They are designed as a double lumen tube with 2 cuffs and separate 15 mm connectors for isolating and ventilating one lung during surgical procedures.



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Indications:

Indications for Use -- The Silbroncho® is used to isolate the left or right lung of a patient for surgery, one lung ventilation or one lung anesthesia.

Patient Population -- Patients requiring one lung isolation

Environment of Use -- Hospitals – OR and ICU

Comparison to Predicate Devices:

	Fuji Silbroncho®	Predicates
Attributes		
Indications for use	The Silbroncho® is used to isolate the left or the right lung of a patient for surgery, one lung ventilation or one lung anesthesia	Same as Mallinckrodt Broncho-Cath K771219
Environments of use	Hospital – OR and ICU	Same as Mallinckrodt Broncho-Cath K771219
Patient Population	Patients undergoing surgical procedure requiring isolation of one lung	Same as Mallinckrodt Broncho-Cath K771219
Technology		
Material	Tube – Silicone Cuff – Silicone Connectors - Polyethylene	Mallinckrodt Broncho-Cath K771219 Tube – PVC Cuff – PVC Vitaid Wire reinforced ET tube K932647 (manufactured by Fuji) Tube and Cuff silicone Connectors - polyethylene
Sizes	33 to 39 French	35 to 41 French Mallinckrodt Broncho-Cath K771219
Design features	Double lumen shaft, 2 cuffs, stylet, Carlens adapter	Same as Mallinckrodt Broncho-Cath K771219

Differences Between Other Legally Marketed Predicate Devices

There are no significant differences between the proposed device, Fuji Silbroncho® tube, and the identified predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2005

Mr. Paul E. Dryden
FUJI Systems Corporation
6329 W. Waterview Court
McCordsville, Indiana 46055-9501

Re: K051522
Trade/Device Name: Silbroncho Double Lumen Tube
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/bronchial differential ventilation tube
Regulatory Class: II
Product Code: CBI
Dated: June 7, 2005
Received: June 8, 2005

Dear Mr. Dryden:

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.

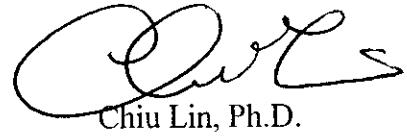
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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 (240) 276-0120. 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.3 Indications for Use

510(k) Number: K051522 (To be assigned)

Device Name: Silbroncho® Tube

Indications for Use: The Silbroncho® is used to isolate the left or the right lung of a patient for surgery, one lung ventilation or one lung anesthesia.

Prescription Use XX **or** **Over-the-counter use** __
(Per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K051522