K981203
1 of 2

JUN 5 1998

RÜSCH
INTERNATIONAL
Group Regulatory Affairs
A Subsidiary of Teleflex Incorporated (USA)

Tall Pines Park
Jaffrey, NH 03452
(603) 532-7706
FAX (603) 532-8211 or 6108

510(k) Summary

1. Submitter Name, Address, and Date of Submission.

Mr. James R. Whitney
Group Regulatory Affairs Associate
Tall Pines Park
Jaffrey, New Hampshire 03452

Telephone: (603) 532-7706
Facsimile: (603) 532-8211
E-Mail: jrwhitney@compuserve.com

Contact: Same as above

2. Name of the Device, Common, Proprietary (if Known), and Classification.

Classification Name: Tube, Gastrointestinal and Accessories

Common Name: Sengstaken Blakemore Tube

Proprietary Name: Rüsch Blakemore Tube - 3 Lumen, sterile

3. Identification of the legally marketed device to which the submitter claims equivalence.

The Rüsch Blakemore Tube - 3 Lumen, sterile is substantially equivalent to the Rüsch Blakemore Tube - 3 Lumen, non sterile.

4. Description of the Device.

The Rüsch Blakemore Tube - 3 Lumen, sterile, consists of a radiopaque ($BaSO_4$), three lumen, soft red rubber, graduated, tube which is rounded and sealed at the distal end and belled out to form a funnel at the proximal end. Four elongated eyes are cut in the tube between the rounded distal (patient) end and the cuffs. Two SILKOLATEX™ cuffs are inflated via separate color identified funnels using any Luer syringe; pilot balloons are provided to indicate cuff inflation. The Rüsch Blakemore Tube - 3 Lumen, sterile, will be available

in three (3) sizes designated by outside diameters Ch 14, 16, 18(14, 16, 18 Fr) and three unique part numbers that are yet to be determined.

The device will be sold sterile, individually packed in a paper-film pack. Two devices will be packaged in a cardboard box, with one set of instructions for use, and designated as a naso-gastric, double balloon tube that can be passed nasally into the stomach suitable for use in the management of bleeding esophageal varices. The tube works in the principle of applying pressure or tamponade via a latex balloon to the bleeding varix.

5. Intended Use of the Device.

The Rüsch Blakemore Tube - 3 Lumen, Sterile, is a single use, naso-gastric double balloon tube that can be passed nasally into the stomach suitable for use in management of bleeding esophageal varcis.

6. Summary of Technological Characteristics.

The Rüsch Blakemore Tube - 3 Lumen Sterile was developed from the Rüsch Blakemore Tube - 3 Lumen non-sterile which is currently in interstate commerce. The provision of a sterile product is thought to warrant this premarket notification. The Rüsch Blakemore Tube - 3 Lumen will be available sterile and non-sterile in sizes 14, 16, and 18 Fr.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 5 1998

Mr. James R. Whitney
Group Regulatory Affairs Associate
RUSCH International
Tall Pines Park
Jaffrey, NH 03452

Re: K981203
Rusch Blakemore Tube - 3 Lumen
Dated: March 30, 1998
Received: April 2, 1998
Regulatory Class: II
21 CFR 876.5980/Procode: 78 KNT

Dear Mr. Whitney:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K981203

510(k) Number (if known):_____

Device Name: Rüsch Blakemore Tube - 3 Lumen, sterile

Indications for Use:

The Rüsch Blakemore Tube - 3 Lumen, Sterile, is a single use, naso-gastric double balloon tube that can be passed nasally into the stomach suitable for use in management of bleeding esophageal varcis

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981203

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