K991580

FEB 4 2000

Attachment 1

510(k) Summary

§807.92(a)(1)

Submitter's Name:
C.L. McIntosh & Associates for The Laryngeal Mask Company Ltd.

Submitter's Address:
12300 Twinbrook Parkway
Suite 625
Rockville, MD 20852

Submitter's Telephone Number:
(301) 770-9590

Contact Person:
Robert L. Sheridan

Date of Preparation:
April 5, 1999

§807.92(a)(2)

Trade/Proprietary Name:
ILM Endotracheal Tube (ILM ETT)

Common/Usual Name:
Endotracheal Tube

Classification Name:
Tracheal Tube

§807.92(a)(3)

Legally Marketed Predicate Device:
Euromedical™ ILM (Intubating Laryngeal mask) 100% Silicone Wire-Reinforced Endotracheal Tube

§807.92(a)(4)

Description of Subject Device:
The ILM ETT is a straight, cuffed, wire-reinforced tracheal tube, with a Murphy Eye. It is available in a three sizes with internal diameters of 7.0mm, 7.5mm and 8.0mm.

The airway tube is made from silicone and features a stainless steel reinforcing wire to prevent kinking or occlusion of the tube. The tip of the tube is molded from a softer grade of silicone for passage through the vocal cords. The airway tube features an inflatable silicone cuff for sealing the tube in the trachea. The tip of the ILM ETT is beveled in two directions to aid passage of the tube through the trachea.

Depth markings are printed on the airway tube (in centimeters). These indicate the distance to the distal tip of the tube. The tube also has a printed black line to indicate its caudal surface.

The ILM ETT features a small diameter silicone tube connected to a pilot balloon with a luer check valve for inflation of the cuff.

The ILM ETT can be connected to the anesthesia circuit by a removable 15mm standard male connector which conforms to ISO5356-1 (1987). A connector is supplied with each ILM ETT.

The ILM ETT is designed to be compatible with the LMA-Fastrach (an oropharyngeal airway). To ensure compatibility, a marker line indicates when the tube passes through the LMA-Fastrach. In addition, the inflation line is mounted close to the rear of the ILM ETT to ensure unobstructed passage of the tube through the LMA-Fastrach.

§807.92(a)(5)

Statement of Intended Use:

The ILM ETT is indicated for airway management by oral intubation of the trachea.

§807.92(a)(6)

Comparison with Predicate Device:

The ILM ETT and the Euromedical Silicone Wire-Reinforced Endotracheal Tube have identical performance, and with the exception of the labeling, they are the same device. The two devices use the same materials and are dimensionally identical. They are molded and assembled in the same manufacturing plant to the same specifications (except for the labeling). The differences in the labeling are limited to changes in the company details, product names and attempts to make the Instructions for Use more readable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 4 2000

Mr. Robert L. Sheridan
The Laryngeal Mask Company Ltd.
c/o C.L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, MD 20852

Re: K991580
ILM Endotracheal Tube
Regulatory Class: II (two)
Product Code: 73 BTR
Dated: November 5, 1999
Received: November 8, 1999

Dear Mr. Sheridan:

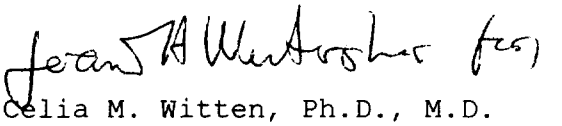
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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) 594-4648. 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,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 3

Indications for Use Statement

Applicant: The Laryngeal Mask Company Ltd

510(k) Number (if known):

Device Name: ILM Endotracheal Tube

Indications for Use: The ILM Endotracheal Tube is indicated for airway management by oral intubation of the trachea.

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓ Prescription Use

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K991580