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XOMED®

K993582

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS K_____

1.0 Date Prepared
October 14, 1999

2.0 Submitter (Contact)
Roy Berens
Xomed Surgical Products
Jacksonville, FL
Telephone: 904-296-645

3.0 Device Name

Proprietary Name:	Laser-Shield® II
Common Name(s):	Tracheal Tube, Endotracheal Tube
Classification Name:	Tracheal Tube

4.0 Device Classification

Tracheal Tube	Product Code	73BTR Class II	21 CFR 868.5730	Tier II

5.0 Device Description
Xomed Laser-Shield II is an endotracheal tube provided sterile with laser resistant overwraps of aluminum and fluoroplastic covering the silicone elastomer shaft. The tube is fitted with an inflatable cuff designed to provide tracheal seal. The inflation assembly/balloon contains dry methylene blue that mixes with a liquid inflation media (sterile normal saline) to provide visible detection of inadvertent cuff rupture by the laser. Sterile cottonoid patties are also provided for wetting and placement around the positioned and inflated cuff for additional heat sink.

6.0 Intended Use
Xomed Laser-Shield II is intended for endotracheal intubation. It is indicated for use for all types of surgical procedures involving carbon dioxide (10.60 microns) or KTP (532 nm) laser use (normal pulsed or continuous beam delivery in the non-contact mode), when endotracheal intubation is required to administer anesthesia gases or to overcome emergency obstruction of an airway.

7.0 Substantial Equivalence
The modified Xomed Laser-Shield II is identical to the current device with the exception of the extension of the aluminum wrap under a portion of the cuff and covering of this extension with a flexible silicone sleeve. The intended use and claims for the modified device remains unchanged and no new materials are being used.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 0 2000

Mr. Roy Berens
Xomed, Inc.
6743 Southpoint Drive North
Jacksonville, FL 32216-0980

Re: K993582
Modification to Laser-Shield® II Endotracheal Tube
Regulatory Class: II (two)
Product Code: 73 BTR
Dated: October 20, 1999
Received: October 22, 1999

Dear Mr. Berens:

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,

Joanna M Waterhouse for,

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

Premarket Notification [510(k)] for Modification to Laser-Shield® II

Intended Use Statement

510(k) Number (if known): K 993582

Device Name: Modification to Laser-Shield II

Indications for Use: Laser-Shield II is intended for endotracheal intubation. It is indicated for use for all types of surgical procedures involving carbon dioxide (10.60 microns) or KTP (532 nm) laser use (normal pulsed or continuous beam delivery in the non-contact mode), when endotracheal intubation is required to administer anesthesia gases or to overcome emergency obstruction of an airway.

(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 Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993582