JUN - 3 1997

510(k) Summary

LuMax Cystometry Tube Set

General Information

Classification Class II

Trade Name	LuMax Cystometry Tube Set
Submitter	MedAmicus, Inc. 15301 Highway 55 West Minneapolis, MN 55447
Contact	Dennis S. Madison Vice President of Administration and regulatory Affairs (612) 559-2613

Predicate Devices

Administration tube set from North American Sterilization and Packaging Company (NASP).

Device Description Information

Intended Use

The LuMax Cystometry Tube Set is intended to be used in the exact same manner as the previous tube sets manufactured by NASP and cleared by FDA under K911865/B. The intended use of these tube sets is to provide a conduit from a liquid resevoir to the infusion lumen of a bladder pressure catheter.

Device Description

The LuMax Cystometry Tube Set consists of a vented spike with a drip chamber for connection to the liquid reservoir, usually a one to three liter saline or DI water bag, a roller clamp for regulating fluid flow rates, and a male luer lock connector for connecting to the filling lumen of the bladder catheter. It is assembled with polyurethane tubing giving it an overall length of 72 inches.

The materials used in the manufacture of the tube set are used in similar tubing sets and in urologic catheters. The methods of packaging and sterilization are the same as MedAmicus uses in its Fiberoptic Catheter line.

Device Performance / Product Testing

Sample devices will be subjected to physical bench testing. Tests will include visual examination for workmanship, tensile strength testing and pressure withstand testing. All samples will meet the required specifications. Test descriptions and specifications are contained in Attachment H.

Sterilization Information

The sterilization cycle for the LuMax Cystometry Tube Set will be identical to the cycle for the Urodynamic Fiberoptic Catheters.The ETO sterilization cycle for these products was validated using the AAMI method of three half cycles and one full cycle.

Validation tests were performed with spore strips (one million spores of Bacillus var niger) placed in sample product and sterilized at one half the regular cycle. The results showed a complete kill which proves a Sterility Assurance Level (SAL) of better than 10^{-6}. See Attachment D for further information.

Packaging

The packaging materials for the package are identical to the MedAmicus Urodynamic Fiberoptic Pressure Catheter products. The product is placed within a sealed Tyvek Pouch. The sterile product, with appropriated labeling, is then placed in a carton for shipping.

Substantial Equivalence

The LuMax Cystometry Tube Set is intended to provide a conduit from a saline or DI resevoir and the infusion lumen of a bladder pressure catheter. The basic design, methods of manufacturing, and materials used are identical to existing administration tube sets cleared by the FDA. Our application of this device is substantially equivalent to the aforementioned standard medical devices already approved for use. The clinical indications for use remain unchanged. MedAmicus believes the LuMax

Cystometry Tube Set is substantially equivalent to currently marketed medical administration tube sets employing the same technology.

Conclusion

In conclusion, MedAmicus believes the LuMax Cystometry Tube Set is substantially equivalent to the predicate administration tube sets. The intended use, materials, sterilization, packaging, labeling, and method of operation and manufacturing methods are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 1997

Mr. Dennis S. Madison
Vice President of Administration
and Regulatory Affairs
MedAmicus, Inc.
15301 Highway 55 West
Plymouth, Minnesota 55447

Re: K971911
LuMax Cystometry Tube Set
Dated: April 24, 1997
Received: April 28, 1997
Regulatory Class: II
21 CFR 876.1620/Procode: 78 FEN

Dear Mr. Madison:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4616. 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/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

510(k) Number (if known): K971911

Device Name: CYSTOMETRY ADMINISTRATION TUBING SET

Indications For Use:

The LuMax Cystometry Tube Set is to be used to provide a conduit from a liquid reservoir to the infusion lumen of a bladder catheter whenever filling a bladder is required in conjunction with performing a Urodynamic Cystometry test .

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter R Rathbun

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971911

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

(Optional Format 1-2-96)