

K974561



FEB 19 1998

1100 Northside Drive Atlanta, Georgia 30318

(Revised) February 12, 1998

Premarket Notification [510(k)] Summary

Submitter: American Medical Devices, Inc
1100 Northside Drive
Atlanta, GA 30318
Phone: (404) 815-5233
Fax: (404) 815-5235

Official Correspondent: Frank J. Tighe

Trade Name: The American Medical Devices, Inc., Moistair™ Fluid/Air Tubing Set.

Common Name: Fluid/Air Tubing Set

Registration Number: We have registered but have not received our application back as of this date.

Class: Class II

Class Name/Number: 880.5725

Panel: Ophthalmic

Product Code: FRN

Device Description: During a vitrectomy, it is necessary to irrigate balanced salt solution (BSS) into the eye to replace the natural vitreous. If a retinal hole is present, the surgeon must then replace the balanced salt solution (BSS) with air to prevent the fluid from remaining under the retina. One of the problems associated with fluid/air exchange is development of cataracts. The Moistair™ Tubing Set humidifies the dry air prior to introduction into the eye. In order to humidify the air, 1 cc of balanced salt solution (BSS) is injected into the injection port on the humidifying filter prior to use.

Statement of indications for use. - **For infusion of fluid and air during vitrectomy**

Substantial Equivalence Comparison

	American Medical Devices, Inc.	Grieshaber & Co.
Packaging Tyvek to Poly	X	X
For infusion of fluid and Air during vitrectomy	X	X
Materials: PVC Tubing Line, .22 micron Filter, Stopcock, IV Spike	X	X
Sterilization ETO	X	X
Humidifying Filter	X	

Sterility

The Device will be ETO Sterilized.

The method used to validate the sterilization cycle is AAMI Overkill Method

Packaging Material: Tyvek Pouch with a Ploymylar Sheath.

The SAL is 10 to the -6.

The maximum levels of residues of **ethylene oxide**: 25 parts per million; **ethylene chlorohydrin**: 25 parts per million and **ethylene glycol**: 250 parts per million.

This device is non-pyrogenic and the LAL Method is used to make that determination.

Pyrogens: We control the manufacturing environment to lessen the likelihood of pyrogen causing bacteria. In addition the LAL Method is used to determine that each lot is non-pyrogenic.

Materials Use In Manufacture: PVC Tubing, .22 Micron Millipore Filter, PVC 3-way stopcock, Plastic Drip Chamber, Plastic Humidifying Filter.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 1998

Mr. Frank J. Tighe
Offical Correspondent
American Medical Devices, Inc.
1100 Northside Drive
Atlanta, GA 30318

Re: K974561
Trade Name: Moistair™ Fluid Air Tubing Set
Regulatory Class: II
Product Code: 80 FRN
Dated: December 3, 1997
Received: December 5, 1997

Dear Mr. Tighe:

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.

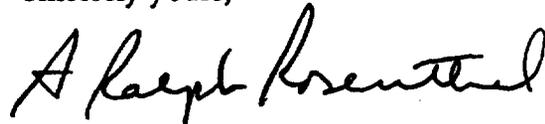
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Frank J. Tighe

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K974561

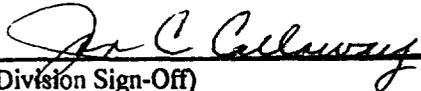
Device Name: Moistair Fluid Air Tubing Set

Indications For Use:

For infusion of fluid and air during vitrectomy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K974561

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-f-6)