

**510(k) Summary**

APR 10 1998

- 1. **Submitter Name:** Applied Medical Technology, Inc.
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Cleveland, OH 44128 USA
- 3. **Telephone:** 216-475-5577
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- 5. **Contact Person:** Tom Parkinson - Quality Assurance / Regulatory Affairs
- 6. **Date of preparation:** January 13, 1998
- 7. **Device Trade or Proprietary Name:** AMT Decompression Tubes
- 8. **Device Common Name:** Decompression Tubes
- 9. **Device Classification Name:** Gastrointestinal Tube Accessories (78KGC)
- 10. **Substantial Equivalency is claimed against the following devices:**

- 1. Applied Medical Technology, Inc. - Decompression Tubes - K920894
- 2. Microvasive/Boston Scientific Corp. - One Step Button and Replacement Button  
Decompression Tubes
- 3. C.R.Bard - One Step Button Decompression Tubes

**11. Device of Description:**  
Decompression device attached to a 12" piece of PVC tubing with a 16 French connector on the other end. The Decompression part is injection molded of Polyethylene in various diameters (French sizes) and Lengths (in cm), either right angle or straight. The proper length is determined by the length of the gastrointestinal button (ie: One Step Button, AMT Button) placed in the patient. By inserting the decompression tube, the gastrointestinal button's internal anti reflux valve is opened, allowing a pathway for patient stomach gasses to escape (decompression). The devices are sold in various sizes, packaged individually with Directions For Use, non-sterile, single user, and disposable.

**12. Intended Use:**  
The AMT Decompression Tubes are intended to be used with the AMT Button, AMT One Step Button, AMT Replacement Button, Microvasive One Step Button, Microvasive Button, Microvasive Replacement Button, (along with similar gastro button feeding devices distributed by Bard, Circon, Surgitek and others). The AMT Decompression Tubes allow gaseous decompression of patients using the Button by opening internal anti-reflux valve, thus allowing gas to escape giving comfort to the patient.

**13. Safety and Effectiveness of the device:**  
The AMT Decompression Tubes are as safe and effective as other predicate devices cited above.

**14. Summary comparing technological characteristics with other predicate devices:**  
The AMT Decompression tubes are identical in design and manufacture, using the same materials and processes used in 510(k) K920894 of Applied Medical Technology, Inc.

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Thomas W. Parkinson  
Leader - Quality Assurance / Regulatory Affairs  
Applied Medical Technology, Inc.  
15653 Neo Parkway  
Cleveland, OH 44128

Re: K980145  
AMT Decompression Tube  
Dated: January 13, 1998  
Received: January 15, 1998  
Regulatory Class: II  
21 CFR 876.5980/Procode: 78 KGC

APR 10 1998

Dear Mr. Parkinson:

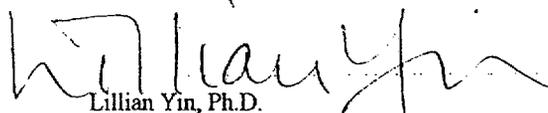
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

**SECTION - I**

**I.5. - INDICATIONS FOR USE STATEMENT**

The AMT Decompression Tubes are used to allow decompression of gasses from a patient's stomach when the patient is using an AMT Button, AMT One Step Button, BARD Button, Surgitek One Step Button, Microvasive One Step Button, AMT Replacement Buttons, or other similar button feeding device that has an anti-reflux valve incorporated. By inserting the proper size decompression tube into the button feeding port, the decompression tube will open the anti-reflux valve, allowing patient stomach decompression without damaging the anti-reflux valve. Opening the anti-reflux valve relieves gaseous pressure in the patient's stomach by allowing the gas to escape through the decompression tube providing comfort to the patient. Other uses are not recommended.

Robert D. Rattling /  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K 980145

Prescription Use ✓  
(Per 21 CFR 801.109)

Over-the-Counter Use \_\_\_\_\_