Atrion Medical Products, Inc.
1426 Curt Francis Road
Post Office Box 564
Arab, AL 35016
Tel 205 586 1580
Fax 205 586 8529

K972964

OCT 10 1997

Atrion Medical

12. SUMMARY OF SAFETY AND EFFECTIVENESS

Date of Preparation: August 7, 1997

Device Name: Atrion Medical Balloon Catheter Inflation Device

Classification Name: Balloon Inflation/Deflation Device

Manufacturer: Atrion Medical Products, Inc.
PO Box 564, 1426 Curt Francis Road
Arab, AL 35016

Contact: Mr. Dan Clark, Atrion Medical Products, Inc.
PO Box 564, 1426 Curt Francis Road
Arab, AL 35016
Telephone: (205) 586-1580, Fax: (205) 586-5553

Predicate: Ryder International Urological Balloon Catheter (Bard® Eagle™) Inflation Device cleared under K962611.

Device Description/Intended Use:

The Atrion Medical Balloon Catheter Inflation Device consists of a plastic syringe with a screw-type plunger and a locking lever and rotating palm grip that control the plunger, a manometer to measure pressure and a connecting tube.

The Device has a fluid capacity of 20 cc and an operating pressure range of vacuum to between 10 and 20 atm, depending on the manometer attached.

The inflation device is intended for single use while performing balloon dilation procedures to inflate the balloon, monitor the pressure within the balloon and deflate the balloon.

Technological Characteristics:

The Atrion Medical Balloon Catheter Inflation Device has an operating pressure range of vacuum to between 10 and 20 atm, depending on the manometer attached, while the predicate device has a range of vacuum to 20 atm. The Atrion Medical Balloon Catheter Inflation Device has no stopcock, while the predicate device does. There are no other significant technological characteristics that distinguish the two devices, and no differences that should pose a risk to patient safety.

Summary of Safety Testing:

The materials of the device which contact the contrast solution in use have been tested using USP guidelines and the results of these studies indicate that the product is safe for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 1997

Mr. Dan Clark
Vice President, Regulatory and Quality
Atrion Medical Products, Inc.
1426 Curt Francis Road
P.O. Box 564
Arab, Alabama 35016

Re: K972964
Atrion Medical Balloon Catheter Inflation Device
Dated: August 7, 1997
Received: August 11, 1997
Regulatory class: II and I
21 CFR §876.5520/Product code: 78 KOE
21 CFR §886.4350/Product code: 86 HNW

Dear Mr. Clark:

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 requirement, 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/dsmamain.html".

Sincerely yours,

William Yin

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): K972964

Device Name: Atrion Medical Balloon Catheter Inflation Device

Indications For Use:

The inflation device is intended for single use while performing gastrointestinal (GI), gastrouterine (GU) and lacrimal duct balloon catheter dilation procedures to inflate the balloon, monitor the pressure within the balloon and deflate the balloon.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972964

(Optional Format 1-2-96)