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

DUPLICATE

K973633

JAN 16 1998

Atrion Medical

## 11. SUMMARY OF SAFETY AND EFFECTIVENESS

**Date of Preparation:** October 9, 1997

**Device Name:** Atrion Medical Coated Lacrimal Intubation Set, K973633

**Common Name:** Coated Lacrimal Intubation Set

**Classification Name:** Lacrimal Probe / Manual Ophthalmic Surgical Instrument per 21 CFR 886.4350

**Manufacturer:** Atrion Medical Products, Inc.
1426 Curt Francis Road
Arab, AL 35016

**Contact:** Mr. Dan Clark
Atrion Medical Products, Inc.
1426 Curt Francis Road
Arab, AL 35016
Telephone: (250) 586-1580, Fax: (205) 586-5553

**Predicate:** Ryder International Lacrimal Intubation Set, K962151

**Device Description:** The Atrion Medical Coated Lacrimal Intubation Set consists of two malleable stainless steel probes (to facilitate insertion) securely attached to a flexible coated silicone tube of varying thickness. The intubation set is a single-use product, sterilized by radiation.

**Intended Use:** The Atrion Medical Coated Lacrimal Intubation Set is valuable in the reconstruction of the lacrimal outflow system and also useful in canaliculus repair, lacrimal obstruction and complicated and uncomplicated dacryocystorhinostomy procedures.

**Technological Characteristics:** The Atrion Medical Coated Lacrimal Intubation Set will be identical to the predicate except that it will have a coating on the tube to increase lubricity and facilitate insertion.

**Summary of Safety Testing:** Based on biocompatibility testing, including cytotoxicity, hemolysis (in vitro), acute systemic toxicity, intracutaneous toxicity, implantation test and histology of the implant site, we conclude that the new device is substantially equivalent to the predicate device under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2008

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

Re: K973633
Trade/Device Name: Atrion Medical Products Lacrimal Intubation Set
Regulatory Class: Unclassified
Product Code: OKS
Dated: January 8, 1998
Received: January 12, 1998

Dear Mr. Clark:

This letter corrects our substantially equivalent letter of January 16, 1998.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973633

Device Name: Atrion Medical Coated Lacrimal Intubation Set

Indications For Use:

1. Maintenance of lacrimal outflow post primary DCR surgical procedures.

2. Maintenance of lacrimal outflow post failed open DCR surgical procedures with complete obstruction.

3. Reconstruction of the canaliculi.

(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 Ophthalmic Devices
510(k) Number K973633

(Optional Format 1-2-96)