

Atrion Medical Products, Inc.

1426 Curt Francis Road

Post Office Box 564

Arab, AL 35016

Tel 205 586 1580

K971100

MAY 23 1997



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SUMMARY OF SAFETY AND EFFECTIVENESS

Date of Preparation:

March 24, 1997

Device Name:

Atrion Medical Autogenous Tissue Collector

Common Name:

Autogenous Tissue Collector

Classification Name:

Component (or accessory) to a Dental Operative Unit per 21 CFR Section 872.6640

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:

SciTech Clearline® Filter, K930144

Device Description:

The Atrion Medical Autogenous Tissue Collector consists of a screen, a gasket, screen support, plastic cover and elastomer tube. The device is a single-use product, sterilized by gamma or E-Beam irradiation.

Intended Use:

The Atrion Medical Autogenous Tissue Collector is useful in the collection of bone or other tissue for reconstruction, implants and repair procedures, for collection of tissue for pathological analysis and for retrieving root tips and precious metals.

Technological Characteristics:

Both the Atrion Medical device and the predicate device consist of a plastic housing containing a polymer screen. The Atrion Medical device consists of a screen, gasket, screen support, elastomer tube and plastic housing while the predicate device consists of an acrylic cartridge housing containing a screen.

Summary of Safety Testing:

Based on the 510(k) "Substantial Equivalence" decision-making process and the information provided herein, we conclude that the new device is substantially equivalent to the predicate device under the Federal Food, Drug and Cosmetic Act.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 1997

Mr. Dan Clark
Vice President Regulatory and Quality
Atrion Medical Products, Incorporated
1426 Curt Francis Road
Arab, Alabama 35016

Re: K971100
Trade Name: Atrion Medical Autogenous Tissue Collector
Regulatory Class: I
Product Code: EIA
Dated: March 24, 1997
Received: March 26, 1997

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.

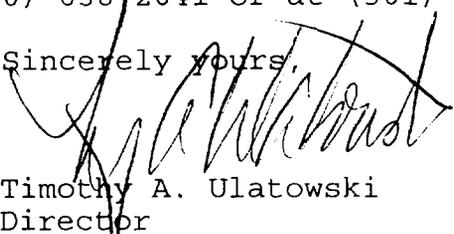
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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) 594-4618. 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 at (301) 443-6597.

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Not known at this time

Device Name: Atrion Medical Autogenous Tissue Collector

Indications For Use:

1. For collection of bone or other tissue for reconstruction, implants and repair procedures.
2. For collection of tissue for pathological analysis.
3. For retrieving root tips and precious metals.

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

Susan Ruma
~~(Division Sign-Off)~~

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number KA7100

Prescription Use ✓

(Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

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