

MAY 17 2000

K993592

SUMMARY
SAFETY AND EFFECTIVENESS for
510(K) OF AXIOM MULTIPURPOSE WOUND DRAIN

In compliance with the requirements of section 510(k) of the Food, Drug, and Cosmetic Act as amended, and 21 CFR Section 807.92(a)(1). This "510(k) Summary" is on a product we intend to market in 90 days.

- (1) Submitter's name, address, telephone number, contact person, date of preparation

Company name: Axiom Medical Inc.
Address: 555 W. Victoria Street
Rancho Dominguez, Ca. 90220
Phone number: (310) 898 - 1779
Fax number: (310) 632 - 1326

Contact person: Ridwan Hardy

Date of preparation: 10/01/1999

- (2) Name of the device

Trade Name: Axiom Multipurpose Wound Drain
Common Name: Irrigation Drainage Catheter
Classification Name: Anesthesia Conduction Catheter
(Per 21 CFR 868.5120)

- (3) Identification of predicate devices

Axiom Sump Drain with Filter
Axiom Interpleural Anesthesia Catheter

- (4) Description of the device

This Axiom Multipurpose Wound Drain is simplicity of design assures effective operation with added convenience. It is a conveniently sized double Lumens Catheter made of silicone round drain with radiopaque line that allows assessment of drain placement after wound closure. Various sizes starting from 14 Fr. up to 36 Fr. coated or no coated will be offered. The first Lumen has a bigger inside diameter than the second lumen, and has a series of port openings (Eyes) into a passageway in the catheter wall that terminates at the first proximal end and connected with polypropylene Christmas tree connector as a fluid outlet (Drainage function). The Catheter equips with suture ring to secure the catheter in the position.

Christmas tree connector as a fluid outlet (Drainage function). The Catheter equips with suture ring to secure the catheter in the position.

(5) Intended use of the device

For use where a routine drainage tube is required to drain fluids and exudates during or after surgery. The additional lumen allows for sump gravity, irrigation function or application of anesthetic to relieve postoperative pain.

(6) Comparison to predicate devices

This device is substantially equivalent in material, indications for use, sterility, drainage and irrigation function with the predicate devices. The lumen of Axiom Multipurpose Wound Drain is designed with full internal diameter and various lengths for drainage and irrigation function. Suture Ring is provided on each catheter to secure the position of the catheter in the body.

(7) Performance data

The test results demonstrate that the device is substantially equivalent to the legally marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 17 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ridwan Hardy
Development Engineer
Axiom Medical, Incorporated
555 West Victoria Street
Rancho Dominguez, California 90220

Re: K993592
Trade Name: Axiom Multipurpose Wound Drain
Regulatory Class: II
Product Code: FRN
Dated: March 13, 2000
Received: March 14, 2000

Dear Mr. Hardy:

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 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 premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

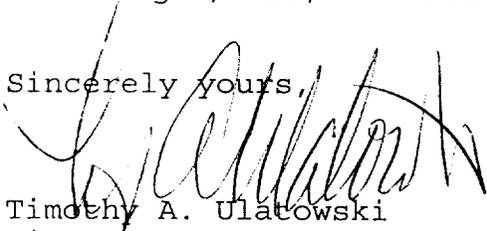
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4692. 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,



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

Enclosure

**EXHIBIT F
STATEMENT OF INDICATIONS FOR USE**

510(K) Number (if Known): ^{was} ~~N/A~~ K993592

Device Name: Axiom Multipurpose Drain

Indications For Use:

Typical applications include:

- For use where a routine drainage tube is required to drain fluids and exudates during surgery or after surgery. The additional lumen allows for sump gravity, irrigation function or application of local anaesthetic to relieve postoperative pain.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____


(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993592