K971851

AXIOM MEDICAL, INC.

555 West Victoria
Rancho Dominguez, California 90220
Telephone 310-898-1779 • Facsimile 310-632-1326

JAN 22 1998

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.

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 Submission: 05/16/1997

1. 0 DEVICE NAMES

1.1 Trade Name: Axiom Interpleural Anesthesia Catheter

1.2 Common Name: Anesthesia Catheter

1.3 Classification Name: Anesthesia Conduction Catheter
(Per 21 CFR section 868.5120)

2.0 PRODUCT DESCRIPTION

This Axiom Interpleural Anesthesia Catheter is simplicity of design assures effective operation with added convenience.
(see Exhibit A: Photograph and Exhibit B: Engineering Drawing)
The sterile single patient use component includes the following:

2.1 A conveniently sized two Lumen Catheter made of Silicone round drain with radiopaque line that allows assessment of drain placement after wound closure. Various sizes starting from 18 Fr. up to 28 Fr. will be offered.

2.2 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 Funnel as a fluid outlet (Drainage function).

2.3 The second Lumen connected to the second Funnel as a fluid inlet (Irrigation function) and the Funnel is equipped with a three-way or four-way Stopcock.

3.0 SUBSTANTIAL EQUIVALENCE COMPARISON

This device is substantially equivalent in sterility, material and drainage function with our Mills Filtered Mediastinal Sump, also is substantially equivalent in indications for use to Interpleural Anesthesia Kit with Polyurethane Catheter marketed by Arrow International, Medical Disposable Inc. and Baxter Pharmaseal. These companies offer Interpleural Anesthesia Kit and teflon epidural catheter.

4.0 INTENDED USE OF THE DEVICE

Typical applications include:

- For use where a routine chest tube is required to drain fluids and exudates during surgery or after surgery. The additional lumen allows for application of topical anaesthetic to relieve pleural pain.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 1998

Mr. Ridwan Hardy
Axiom Medical, Inc.
555 West Victoria Street
Rancho Dominguez, CA 90220

Re: K971851
Interpleural Anesthesia Catheter
Regulatory Class: II (two)
Product Code: 73 BSO
Dated: November 3, 1997
Received: November 5, 1997

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 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) 594-4648. 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if Known): K971851

Device Name: Axiom Interpleural Anesthesia Catheter

Indications For Use:

Typical applications include:

- For use where a routine chest tube is required to drain fluids and exudates during surgery or after surgery. The additional lumen allows for application of local anaesthetic to relieve postoperative pain. Caution: The Delivery of local anaesthetic is intended for duration of use, less than 72 hours.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

M Price

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971851

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Revised: 01/16/98