K983900

JAN 29 1999

SAFETY AND EFFECTIVENESS SUMMARY
Advanced Medical Technology Limited Venometer

Name and address of Device Manufacturer submitting 510(k) Notification:

Advanced Medical Technology Limited
15 Trench Road, Mallusk, Co Antrim
Northern Ireland, BT36 4TY
United Kingdom

Regulatory Correspondent of Device Manufacturer:

Dr. Andrew Barr
Advanced Medical Technology Limited
15 Trench Road, Mallusk, Co Antrim
Northern Ireland, BT36 4TY
United Kingdom
Phone: +44-1232-341422
FAX: +44-1232-341420

Date Summary was prepared:

October 29, 1998

Name of the device:

Venometer Strain Gauge Plethysmograph

Classification:

Plethysmograph, Hydraulic, (Strain Gauge). Class II per 21CFR 870.2780

Indications for Use:

The Venometer Strain Gauge Plethysmograph is a hydraulic plethysmograph used to estimate the blood flow in thighs and calves of the body. Its primary purpose is as a screening device for deep vein thrombosis.

Description of the device:
The Venometer is a portable instrument with which nurses can test patients at their bedside for potentially fatal blood clots in their legs.

It was developed to tackle the growing problem of hospital bed shortages and waiting lists where these are caused by disease of blood clotting in leg veins (DVT).

The definitive description of a DVT is that it blocks normal blood flow. This feature is exploited innovatively by the Venometer. It first inflates a pressure cuff around the thigh to allow veins to fill with blood, and then releases this pressure and measures this pressure and measures the rate at which the veins subsequently empty.

It automatically calculates the likelihood of a DVT based on these measurements.

Typically 8 out of ten patients with symptoms of DVT do not have the disease, but they only learn this after waiting 2 days in the hospital for an expensive specialist investigation. Using a Venometer, a Nurse can rule out DVT with ten minutes at the bedside, to the benefit of both the patient and hospital.

The Advanced Medical Technology Venometer is a noninvasive measurement system in which a silicon rubber tube filled with an electrically conductive liquid metal is wrapped around a patient's leg. Any change in girth will stretch the tubing, thus changing the resistance of the material in the tubing in proportion to the change in girth. This resistance change is converted by an electronic circuit to a voltage that can be easily measured and recorded.

The electrically conductive liquid metal is an alloy of gallium and indium. This technology is licensed from Medasonics Incorporated, the manufacturer of the predicate device.

A computer has been incorporated into the Venometer to provide step-by-step guidance for the operator throughout the test as a way of minimizing operator error; and to eliminate the need for an operator to consult a chart to make a diagnosis.

Substantial Equivalence:

The Advanced Medical Technology Limited Venometer is substantially equivalent to the following legally marketed device:

Medasonics Incorporated
Fremont, California
Model SPG16 Strain Gauge Plethysmograph
510(k) K782132, cleared 2/26/79

Safety and Efficacy:

In part fulfillment of the essential requirements of European Directive 93/42/EEC and certified by SGS Yarsley ICS, the Risk Analysis of the Venometer which was performed prior to commencement of manufacturer was in accordance with the requirements of European Standard prEN1441:1994.

In part fulfillment of the essential requirements of European Directive 93/42/EEC and certified by SGS Yarsley ICS, the Northern Ireland Technology Centre has tested the Venometer for Electromagnetic Compatibility and has certified the product as in compliance with European Standard EN55011 and in particular meeting the limits specified by Class A as defined in the standard.

In part fulfillment of the essential requirements of European Directive 93/42/EEC and certified by SGS Yarsley ICS, the Venometer is designed and manufactured in compliance with European Standard EN60601-1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 1999

Mr. William E. McKay
Advanced Medical Technology Limited
c/o Romdi
9712 S. Altamont Drive
Sandy, UT 84092

Re: K983900
Venometer
Regulatory Class: II (two)
Product Code: 74 JOM
Dated: October 31, 1998
Received: November 3, 1998

Dear Mr. McKay:

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 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). 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/dsma/dsmamain.html".

Sincerely yours,

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): Not yet assigned K983900

Device Name: **Venometer Strain Gauge Plethysmograph**

Indications For Use:

The Venometer Strain Gauge Plethysmograph is a hydraulic plethysmograph used to estimate the blood flow in thighs and calves of the body. Its primary purpose is as a screening device for deep vein thrombosis.

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

Concurrence of CDRH, Office if Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983900

(Optional Format 1-2-96)