K991469 5

JUL 20 1999

510(k) SUMMARY

This Summary was prepared in accordance with the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

I GENERAL INFORMATION:

Establishment - AAC Consulting Group, Inc.
7475 Wisconsin Ave., Suite 850
Bethesda, MD 20814

Contact Person: Eduardo March, Senior Consultant
Teleph.- 301-986-4440 Fax- 301-986-4448

Device Name - Aware ™ Pad
Classification Name- Mammographic X-ray Systems (CFR 892.1710), Class II

II PERFORMANCE STANDARD: No mandatory performance or voluntary standards are applicable.

III SUBSTANTIAL EQUIVALENCE:
The Aware ™ pad is substantially equivalent to a currently marketed device, the Sensor Pad® (K973450).

III INDICATIONS FOR USE:
The Aware™ Pad is indicated as an aid for performing breast self-examination.

IV TECHNOLOGICAL CHARACTERISTICS:
Aware ™ Pad is a thin polyurethane bladder, 9.5 inches in diameter containing a small quantity of silicone fluid. The very thin nature of the polyester polyurethane allows the pad to conform to the shape of the tissues underlying it. The very low coefficient of friction property of the silicone fluid in combination with the very thin and flexible bladder, provides easy sliding between the upper and lower surfaces of the bladder. Therefore, when properly used between the finger and the soft breast tissues of the patient, a reduction of friction is observed.

Prepared: 19 April 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 1999

Mr. Eduardo March, RAC
Senior Consultant
AAC Consulting Group, Inc.
7575 Wisconsin Avenue, Suite 850
Bethesda, MD 20814

Re: K991469
Aware™ Pad
Dated: April 26, 1999
Received: April 28, 1999
Regulatory Class: II
21 CFR §892.1560/Procode: 90 IYO

Dear Mr. March:

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) 594-4613. 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991469

Device Name: Aware™ Pad

Indications for Use:

The Aware™ Pad is indicated as an aid for performing breast self-examination.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991469

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: (Per 21 CFR 80.109) **OR** **Over-the-Counter Use:** ✓