NOV 2 6 2002

510(K) SUMMARY

K023390

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

1. General Information

- **Device Name and classification:**
  My Breast Friend Breast Self-exam Pad
  - Class II

- **Submitter's Name:**
  MBF Sales LLC

- **Contact Name and address:**
  Eduardo March
  AAC Consulting Group Inc.
  7361 Calhoun Place, Suite 500
  Rockville, MD 20855

2. Performance Standard:

No mandatory or voluntary standards are applicable.

3. Substantial Equivalence:

The My Breast Friend Self-exam Pad is substantially equivalent to the currently marketed devices, Sensor Pad (K973450) and Aware Pad (K991469).

4. Indications for Use:

The My Breast Friend Self-exam Pad is indicated as an aid for performing breast self-examination.

5. Technological Characteristics:

The My Breast Friend Breast Self-exam Pad is a thin polyurethane bladder containing a small quantity of silicone and air fluids. The very thin nature of the material allows the pad to conform to the patient's breast tissue and for the patient to observe a reduction in friction. The very thin and flexible bladder provides easy sliding between the upper and lower surfaces of the bladder and allows the patient to sense subtle tissue density variations.

Date Prepared: 30 September 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 6 2002

MBF Sales LLC
% Mr. Eduardo March
Senior Consultant
AAC Consulting Group
7361 Calhoun Place
Suite 500
ROCKVILLE MD 20855-2765

Re: K023390
Trade/Device Name: My Breast Friend
Self-exam Pad
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: 90 IXH
Dated: October 7, 2002
Received: October 9, 2002

Dear Mr. March:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

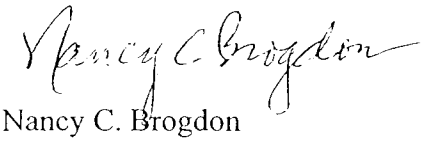
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) NUMBER (If known): K023390

Device Name: My Breast Friend Breast Self-exam Pad

Indications for Use:

My Breast Friend Breast Self-exam Pad is indicated as an aid for performing breast self-examination.

(Please do not write below this line – Continue on other page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

David G. Lepson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023390