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K023229

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Contact: DR. GORDON L. HIXSON
Ms. ADRIAN PALMER

DEC 13 2002

AMERICAN MAMMOGRAPHICS S.O.F.T. PADDLE™
(Special Optimized Full Compression Tray)

510(k) SUMMARY

While mammography is very sensitive in detecting breast cancer, there are areas of concern. Many patients find mammography very uncomfortable. Breast cancers are frequently missed when located in dense breast tissue, particularly anteriorly. Often, the poor compression of anterior tissue results in film retakes and/or the need for diagnostic studies to distinguish dense tissue from masses. However, most existing full breast compression paddles do not adequately compress the anterior half of the breast; conversely the breast near the chest wall is over-compressed causing patient discomfort and sometimes bruising. Good compression of the breast is necessary to obtain satisfactory mammograms. Good compression reduces breast thickness, shortens exposure time, reduces motion blur, permits use of lower kVp resulting in better contrast resolution and spreads apart breast structures which reduces superimposed structures.

AMERICAN MAMMOGRAPHICS, INC. intends to construct a full breast compression device from gamma stabilized LEXAN® or polycarbonate equivalent plastic currently used in the manufacture of numerous radiological and medical devices. The compression device will readily adapt to existing paddle arms from current OEMs and will also be available as a complete device with compression plate, yoke and mounting arm/shaft. The proposed device is a special optimized full breast compression tray called S.O.F.T. **Paddle™** and will allow the targeted area to be imaged accurately, will allow more breast tissue to be imaged, and permit thinning of tissue where it is needed most. The **S.O.F.T. Paddle™** proposes to offer full breast coverage with the compression plate set at an angle, downward from the chest wall toward the nipple, for better compression of anterior structures; thus it is a ***Special Optimized Full Compression Tray***. When used for screening views, additional breast tissue can be compressed from the mid-breast to the nipple with improvement to the imaged area.

This compression device is substanially equivalent to those now marketed by several mammographic equipment manufacturers, such as GE, Lorad, Planmed, Instrumentarium, et al. The compression device is normally placed between the x-ray tube and the breast in order to compress the breast tissue and visualize breast structures, both normal and abnormal. The main advantages of S.O.F.T. PADDLE™ are that patient comfort is improved, breast tissue is more adequately compressed due to the design, positioning against the chest wall side is improved, and less compression force is needed. A greater area of breast tissue can be imaged, contrast resolution of the mammogram is improved, and it is adaptable by retrofit to the original equipment manufacturer's current paddle arms or can be supplied as a complete paddle for brand-specific mammography equipment.

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The compression plate component does not rely on the electrical machinations or rely on the power generated by the machine to accomplish its purpose of compression only. It does not have any impact on the mammographic or x-ray power source. When attached to a paddle/mounting arm the device is dependent upon the electrical power of the mammographic machine to move the compression device up or down, as are all compression paddles for mammography.

The previously issued 510(k) #K903651/B and #K954521 for MammoSpot compression/magnification platforms and MammoSpot Spot Paddle contain applicable equivalent information regarding the efficacy of spot compression both above and below the breast, i.e., a spot cone placed either between the x-ray tube and breast or between the breast and the image receptor and the importance of good breast compression to maximize the quality of a mammogram. Equivalent information regarding chest wall imaging, anterior breast coverage, and maximized compression is also noted in the previously issued 510(k). For Full Breast mammographic examinations, conventional paddles do not adequately compress the anterior half of the breast causing tissue to be superimposed leading to unnecesary retakes and/or diagnostic work-ups. S.O.F.T. Paddle™ would be used between the x-ray tube and the breast but with a sloped or angled design optimizing the full breast compression for a mammographic examination with equal distribution and better thinning of breast tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2002

Ms. Adrian Palmer
Director of Marketing
American Mammographics
1302 Shawhan Terrace
CHATTANOOGA TN 37411

Re: K023229
Trade/Device Name: S.O.F.T. PADDEL™
(Special Optimized Full Compression Tray)
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: 90 IZH
Dated: September 26, 2002
Received: September 27, 2002

Dear Ms. Palmer:

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

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

Enclosure

510(k) Number (if known): K023229

Device Name: S.O.F.T. PADDLE™, MODEL SFT-POLE

Indications For Use:

For use in Screening Mammographic Imaging as a Specialty Paddle for Full Breast Compression as an alternative to conventional breast compression paddles.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hoffman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023229

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

(Optional Format 1-2-96)