IZI MEDICAL PRODUCTS

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K101373

SEP 15 2010

510(k) **Summary**

Device Name:	emBRACE
Classification Name:	Accessory to X-Ray Mammographic System (IZH) 21 CFR 892.1710 Accessory to Scintillation (Gamma) Camera (IYX) 21 CFR 892.1100
Device Classification:	Class II (IZH) Class I (IYX)
Predicate Device:	MammoPad® Radiolucent Cushion
Manufacturer:	IZI Medical LLC 7020 Tudsbury Road Baltimore, MD 21244
Establishment Registration Number:	1123169
Submitter/Official Contact:	Ronald T. Horton IZI Medical Products LLC 7020 Tudsbury Road Baltimore, MD 21244 Phone: (410) 594-9403 (ext 248)

Intended Use:

emBRACE is intended to provide padding for patient comfort and aid in positioning during radiologic visualization of the breast using x-ray technology.

Device Description:
emBRACE is a radiolucent foam cushion used during radiologic visualization of the breast. emBRACE is non-sterile and is a single use device.
emBRACE will be offered in the following configurations for ease of use dependent o the radiological system used:

- Product Number 00283-001 for use on an 18x24cm bucky.
- Product Number 00283-100 for use on a 25x29cm bucky.
- Product Number 00283-200 for use on a 29x30cm bucky.

Technological Characteristics/Performance Data Summary:
emBRACE is equivalent to the predicate device, with the same principles of operation and overall technological characteristics.

IZI Medical Products LLC will provide safety and effectiveness information supporting the FDA finding of Substantial Equivalence to any person within 30 days of a written request.

Conclusion:
Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, emBRACE is determined to be substantially equivalent to an existing legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Helen Zinreich Shafer
CEO
IZI Medical Products
7020 Tudsbury Dr.
BALTIMORE MD 21244

SEP 15 2010

Re: K101373
Trade/Device Name: Embrace Mammography Cushion
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: IZH
Dated: August 11, 2010
Received: August 12, 2010

Dear Ms. Shafer:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

K101373

SEP 15 2010

510(k) Number (if known): K101373

Device Name: embrace Mammography Cushion

Indications for Use:

embrace is intended to provide padding for patient comfort and aid in positioning during radiologic visualization of the breast using x-ray technology.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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