K072515

510(K) SUMMARY
(as required by 807.92(c))

SEP 20 2007

Submitter of 510(k):

Orison Corporation
121 Boone Ridge Dr, Suite 2004
Johnson City, TN 37615
USA

Phone: (423) 282-5919
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Contact Person: Al Sandy

Date of Summary: April 4, 2007

Trade/Proprietary Name: Embrace Gel

Classification Name: Diagnostic, Ultrasonic, Transducer

Product Code: MUI

Intended Use:

Embrace Gel is intended for use as an ultrasound coupling media for use with the Embrace™ 3D Ultrasound Tomography System K070477.

Device Description:

Embrace™ Gel Pad is en expandable polymer used to provide a coupling medium between breast tissue and the Embrace™ 3D Ultrasound Tomography System K070477. The gel is prepared just prior to scanning by placing the gel pad in the dome and adding hydrating fluid. The gel pad expands and fills the voids between the probe and breast tissue. After the ultrasound scan is completed, the gel is removed from the dome in one piece.

Predicate Device:

Aquasonic 100 Ultrasound Trans Gel K802146

Substantial Equivalence:
The Embrace Gel provides an effective coupling between the tissue being examined and the ultrasound unit. Its function and performance are similar to the predicate device as presented in this 510(k)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 20 2007

Orison Corporation
% Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 E. Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K072515
Trade/Device Name: Embrace Gel
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: MUI
Dated: September 6, 2007
Received: September 7, 2007

Dear Mr. Lehtonen:

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 (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 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 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 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:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Indications for Use

510(k) Number (if known): K072515

Device Name: Embrace Gel

Indications for Use:

Embrace Gel is intended for use as an ultrasound coupling media for use with the Embrace™ 3D Ultrasound Tomography System (K070477)

Prescription Use __Yes_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __N/A_____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072515