K102637

FEB 16 2011

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

**Submitter of 510(k):**

Dynarex Corporation
10 Glenshaw Street
Orangeburg, NY 10972
USA
Phone: (845) 365-8200
Fax: (845) 365-8201

**Contact Person:** Daniel Consaga

**Date of Summary:** December 20, 2010

**Trade/Proprietary Name:** Dynarex Ultrasound Gel.

**Classification Name:** Diagnostic Ultrasonic Transducer

**Product Code:** MUI

**Intended Use:**

Dynarex Ultrasound Gel is intended for use as the coupling medium for ultrasound procedures on external, intact skin. Not for use with defibrillators.

**Device Description:**

Dynarex Ultrasound Gel is a viscous, clear blue, water soluble gel. Typical packaging configurations for the Dynarex Ultrasound Gel is 250 ml plastic bottle, 1 Liter plastic bottle and 5-liter plastic container. Other sizes may become available.

**Predicate Device:**

LiquaSonic Ultrasound Gel 510k Number K841871 manufactured by CHESTER LABS, INC. Erlanger, KY 41018.

**Substantial Equivalence:**

The Dynarex Ultrasound 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)

**Safety and Effectiveness of the device:**

This device is as safe and effective as the predicate device cited above.
This is better expressed in the Test Report for ISO 10993 and Test Report Number HIA_DYN_GEL_AM Dated August 27, 2008.

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

**Summary comparing technological characteristics with other predicate device:**
Dynarex Ultrasound Gel is similar in terms of intended use and technological characteristics to predicate devices reviewed as coupling gels used to couple ultrasound devices to skin. The device is substantially equivalent with respect to indications for use and other physical characteristics to predicate devices in terms of section 510(k) substantial equivalency.

Please find below a tabulated comparison supporting that this device is substantially equivalent to the predicate device in commercial distribution.

| TECHNOLOGICAL CHARACTERISTICS | Dynarex Gel Comparison to LiquaSonic Ultrasound Gel – 510K # K841871 |
|---|---|
| **Indications for use** | Substantially Equivalent |
| **Target Population** | Substantially Equivalent |
| **Materials** | Substantially Equivalent |
| **Biocompatibility** | Substantially Equivalent |
| **Anatomical sites** | Substantially Equivalent |

## Performance Summary:

FDA has not established special controls or performance standards for this device.

| TECHNOLOGICAL CHARACTERISTICS Performance | Dynarex Ultrasound Gel 510K # K102637 | LiquaSonic Ultrasound Gel 510K # K841871 |
|---|---|---|
| Acoustic Speed Measurement (m/s) | 1530.1 | 1549.5 |
| Acoustic Attenuation Coefficient – Avg. 3 Lots (dB/cm/MHz) | 0.04 +/- 0.018 | < 0.05 |
| Acoustic Impedance Measurement (MRayl) | 1.505 | 1.561 |
| Electroconductivity Avg. 3 Lots (mS/cm) | 1.930 +/- 0.026 | 1.349 +/- 0.003 |

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

Mr. Daniel Consaga
Quality Engineer
Dynarex Corporation
10 Glenshaw Street
ORANGEBURG NY 10962

FEB 16 2011

Re: K102637
Trade/Device Name: Dynarex Ultrasound Gel
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasound transducer
Regulatory Class: II
Product Code: MUI
Dated: December 20, 2010
Received: January 10, 2011

Dear Mr. Consaga:

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,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K102637

Device Name: Dynarex Ultrasound Gel

Indications for Use:

Dynarex Ultrasound Gel is intended for use as an ultrasound coupling media for use with the any Ultrasound System, Ultrasound procedures including diagnostic and elective pre-natal scans.

Dynarex Ultrasound Gel is an electroconductive gel media used with ultrasonic pulsed echo imaging system. The gel is intended to facilitate projecting a pulsed sound beam into body tissue to determine the depth or location of the tissue interfaces and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver.

Apply the ultrasound gel to the treatment area. Remove after treatment with a tissue or towel. For external use only.

Contraindications: Not for use with defibrillators.

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

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

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Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102637