K021132

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MAY 15 2002

The Ludlow Company LP
Two Ludlow Park Drive
Chicopee, MA 01022

510(k) Summary

Date Prepared: April 3, 2002

Manufacturer	The Ludlow Company LP Two Ludlow Park Drive Chicopee, MA 01022 Registration Number: 1219103
Manufacturing Location	Uni-Patch 1313 West Grant Blvd. Wabasha, MN 55891 Registration Number: 2183164
Contact Person	M. Beth Rice Regulatory Affairs Manager Phone: (413)-593-8266 Fax: (413) 593-7266
Device Trade Name	Uni-Patch Ultrasound Coupling Gel
Common Name	Ultrasound gel
Classification Name	Transmission medium for acoustical coupling
Regulatory Reference	MUI
Predicate Device	Aquasonic 100 Ultrasound Transmission Gel

Description: Uni-Patch Ultrasound Coupling Gel is a viscous, clear blue, water-soluble gel. Typical packaging configuration for the Uni-Patch Ultrasound Coupling Gel is 250 ml plastic bottles and 5 liter plastic containers.

Intended Use Uni-Patch Ultrasound Coupling Gel is intended for use as the coupling medium for Ultrasound procedures on external, intact skin

Physical and Technical Comparison:

Uni-Patch Ultrasound Coupling 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 similar with respect to indications for use and physical characteristics to predicate devices in terms of section 510(k) substantial equivalency.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 5 2002

Ms. M. Beth Rice
Regulatory Affairs Manager
The Ludlow Company, LP
Two Ludlow Park Drive
CHICOPEE MA 01022

Re: K021132
Trade/Device Name: Uni-Patch Ultrasound Coupling Gel
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 MUI
Dated: April 3, 2002
Received: April 9, 2002

Dear Ms. Rice:

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): K021132

Device Name: Uni-Patch Ultrasound Coupling Gel

Indications for Use:

Uni-Patch Ultrasound Coupling Gel is intended to be used as an ultrasound coupling medium on external, intact skin for short duration.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021132