K083358

510(k) Summary

JAN - 9 2009

Submitted by Farco-Pharma GmbH Pharmazeutische Präparate
Address: Gereonsmühlengasse 1 – 11
50670 Köln, Germany
Telephone: +49 221 594061
Contact Name: Kornelia Ely-Koort, Regulatory Affairs Dept.

Date Submitted: December 11, 2008

Trade Name: Lubricano® Sterile Gel – Ultrasound
Common Name: Ultrasound gel
Product Code / Regulation: MUI (21 C.F.R. 892.1570)

Description: Lubricano® Sterile Gel is a sterile, water-soluble gel composed of hydroxyethylcellulose, glycerol, and purified water, which is contained in a 10 mL syringe. Lubricano® Sterile Gel is free from fats, latex, disinfectants and preservatives. Lubricano® Sterile Gel ensures that catheters and instruments move easily, and it adheres well to the mucosa.

Intended Use: Lubricano is an *in vivo* biocompatible and bioexcretable sterile couplant intended for use as a scanning gel in surgical procedures, biopsies and similar sterile applications.

Lubricano is used to couple sound waves between the patient and medical imaging electronic transducers during intraoperative and intracavitary medical diagnostic ultrasound imaging procedures, such as transcutaneous ultrasound image guided biopsy and aspiration, intraoperative ultrasound imaging, intracavity ultrasound imaging, and gel infusion sonography.

Lubricano is unit dose packaged, sterilized and intended for use in all diagnostic ultrasound procedures that currently use an ultrasound coupling gel or other fluid, alone or in combination with a transducer cover, where sterility, *in vivo* biocompatibility and bioelimination are required.

Substantial Equivalence: Lubricano® Sterile Gel is substantially equivalent to the following devices:
SonoTech, Inc.'s UltraBio – In Vivo Biocompatible Bioeliminated Sterile Ultrasound Imaging Couplant (K042619 and K033178), and Farco-Pharma GmbH's Lubricano® Sterile Gel (K081990).

Results of *in vivo* and *in vitro* testing establishes the safety profile of the device as non-toxic, non-irritating and non-sensitizing, which is comparable to the predicate devices.

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Submitted by Farco-Pharma GmbH Pharmazeutische Präparate
Address: Gereonsmühlengasse 1 – 11
50670 Köln, Germany
Telephone: +49 221 594061
Contact Name: Kornelia Ely-Koort, Regulatory Affairs Dept.

Date Submitted: October 1, 2008

Trade Name: Lubricano® Sterile Gel – Ultrasound
Common Name: Ultrasound gel
Product Code / Regulation: MUI (21 C.F.R. 892.1570)

Description: Lubricano® Sterile Gel is a sterile, water-soluble gel composed of hydroxyethylcellulose, glycerol, and purified water, which is contained in a 10 mL syringe. Lubricano® Sterile Gel is free from fats, latex, disinfectants and preservatives. Lubricano® Sterile Gel ensures that catheters and instruments move easily, and it adheres well to the mucosa.

Intended Use: Sterile gel for acoustic coupling in ultrasound indications

Substantial Equivalence: Lubricano® Sterile Gel is similar in intended use and technological characteristics to the predicate device reviewed as coupling gels used to couple ultrasound devices to the skin. The device is similar with respect to indications for use and physical characteristics to predicate device in terms of 510(k) substantial equivalency.

Results of *in vivo* and *in vitro* testing establishes the safety profile of the device as non-toxic, non-irritating and non-sensitizing, which is comparable to the predicate device.

Indications for Use

510(k) Number (if known): _____

Device Name: Lubricano® Sterile Gel – Ultrasound

Indications for Use:

Sterile gel for acoustic coupling in ultrasound indications

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FARCO-PHARMA GmbH
% Mr. Seth A. Mailhot
Attorney
Latham & Watkins LLP
555 Eleventh Street, NW
WASHINGTON DC 20004-1304

JAN - 9 2009

Re: K083358
Trade/Device Name: Lubricano® Sterile Gel - Ultrasound
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: MUI
Dated: December 11, 2008
Received: December 12, 2008

Dear Mr. Mailhot:

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 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 os 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 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, 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.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting 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): K083358

Device Name: Lubricano® Sterile Gel – Ultrasound

Indications for Use:

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083358