K081990

510(k) Summary

Submitted by Farco-Pharma GmbH Pharmazeutische Präparate
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Contact Name: Kornelia Ely-Koort, Regulatory Affairs Dept.

DEC 0 5 2008

Date Submitted: October 1, 2008

Trade Name: Lubricano® Sterile Gel – Transurethral
Common Name: Lubricating jelly for transurethral surgical instrument
Product Code / Regulation: FHX (21 C.F.R. 876.1500)

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 human use, e.g. in medical procedures – to aid the introduction of catheters and endoscopic instruments in transurethral examinations, and in intermittent catheterization – particularly for incontinence treatment.

Substantial Equivalence: Lubricano® Sterile Gel is similar in intended use and technological characteristics to the predicate lubricating jelly for transurethral surgical instruments. The device is similar with respect to indications for use and physical characteristics to the 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.

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

DEC 0 5 2008

Re: K081990
Trade/Device Name: Lubricano® Sterile Gel
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FHX
Dated: November 19, 2008
Received: November 20, 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 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). 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 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,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K081990

Indications for Use

510(k) Number (if known): _____

Device Name: Lubricano® Sterile Gel – Transurethral

Indications for Use:

Sterile gel for human use, e.g. in medical procedures – to aid the introduction of catheters and endoscopic instruments in transurethral examinations, and in intermittent catheterization – particularly for incontinence treatment.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal &
Radiological Devices
510(k) Number K081990