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INGfertility

"Naturally Enhancing Reproduction"™

510(k) Summary
Pre' Vaginal Lubricant

OCT 13 2006

I. General Information on Submitter

Address:	INGfertility, LLC (Subsidiary of Bio-Origyn, LLC) 17206 S. Spangle Creek Rd. Valleyford, WA 99036 USA
Telephone:	509.443.0149
Fax:	509.448.0601
Email:	dclifton@ingfertility.com
Contact Person:	G. Dennis Clifton, Pharm.D.
Date Prepared:	May 18, 2005

II. General Information on Device

Proprietary Name: Pre' Vaginal Lubricant

Classification Name: Lubricant, Vaginal, Patient (21 CFR 880.6375, Product Code MMS)

III. Predicate Devices

Predicate Device	510(k) control #
K-Y Brand Ultra Gel	K020827

IV. Description of Device

This product is a non-sterile, water-based personal lubricant formulated to supplement the body's own natural lubricating fluids. This product may be used to facilitate entry of diagnostic or therapeutic devices, enhance the comfort of intimate sexual activity, or provide personal lubrication when vaginal dryness causes discomfort. The formulation does not harm sperm function and is pH balanced to match fertile cervical mucus. The product is compatible with latex and polyurethane condoms. Following is the ingredient list for Pre' Vaginal Lubricant:

Ingredients
Water
Hydroxyethylcellulose, NF
Pluronic 127, NF
Sodium Chloride, USP
Arabinogalactan
Sodium Phosphate
Carbopol 934P, NF
Methyl Paraben, USP
Sodium Hydroxide, NF
Potassium Phosphate

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V. Intended Use

Pre' has the following intended uses:

- To lubricate vaginal tissues to facilitate entry of a diagnostic or therapeutic devices including fertility interventions.
- As a personal lubricant to supplement the body's own natural lubricating fluids, to moisturize, relieve friction and to enhance the ease and comfort of intimate sexual activity. This lubricant may be safely applied to vaginal or penile tissues for lubrication and moisturization purposes. It is also compatible with latex and polyurethane condoms.

VI. Technological Characteristics of Device Compared to Predicate Device

Pre' shares the following technological characteristics with the predicate device: highly lubricious, medium viscosity, water based, clear, non-irritating, non-sterile, and condom compatible.

VII. Summary of Preclinical Performance Data

Preclinical biocompatibility studies in rabbits revealed no penile or vaginal irritation from Pre'. The Slug Mucosal Irritation Test of the formulation demonstrated no potential for vaginal mucosal irritation. Pre' had no detrimental effects on the ability to fertilize bovine embryos in vivo. Mouse Embryo Assay (MEA) studies with Pre' have demonstrated normal embryo development with no suggestion of toxicity. Pre' has no detrimental effects on human sperm motility parameters, sperm viability or sperm chromatin. Stability of Pre' was confirmed in accordance with FDA and International Conference on Harmonization (ICH) guidelines. The formulation is compatible with latex and polyurethane condoms.

VIII. Summary of Clinical Performance Data

Biocompatibility studies found no evidence of skin irritation or sensitization in humans. Focus groups and consumer-use testing demonstrates that Pre' is non-irritating and very effective as a personal lubricant.

IX. Conclusion

Laboratory, preclinical, and clinical testing conducted with Pre' Vaginal Lubricant has provided scientific evidence that this product is safe for its intended use and substantially equivalent to the predicate device KY® Brand Ultra Gel™.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 10, 2014

INGfertility, LLC
G. Dennis Clifton, Pharm.D.
Vice President
17206 South Spangle Creek Road
Valleyford, WA 99036

Re: K051436
Trade/Device Name: Pre' Vaginal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: PEB
Dated: September 14, 2006
Received: September 15, 2006

Dear Dennis Clifton,

This letter corrects our substantially equivalent letter of October 13, 2006.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051436

Device Name: Pre' Vaginal Lubricant

Indications for Use:

- To lubricate vaginal tissues to facilitate entry of a diagnostic or therapeutic devices including fertility interventions.
- As a personal lubricant to supplement the body's own natural lubricating fluids, to moisturize, relieve friction and to enhance the ease and comfort of intimate sexual activity. This lubricant may be safely applied to vaginal or penile tissues for lubrication and moisturization purposes. It is also compatible with latex and polyurethane condoms.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use __X_____ (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)

David A. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051436