U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(jsh)
FOLDER:	K072741 - 650 pages
COMPANY:	INGFERTILITY, LLC (INGFERTILITY)
PRODUCT:	LUBRICANT, PATIENT, VAGINAL, LATEX COMPATIBLE (NUC)
SUMMARY:	Product: PRE-VA VAGINAL LUBRICANT
DATE REQUESTED:	Nov 2, 2011
DATE PRINTED:	Nov 2, 2011
Note:	Printed

K072741

510(k) Summary
Pre~Va Vaginal Lubricant

JUL 16 2008

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:	509.471.9638
Email:	dclifton@ingfertility.com
Contact Person:	G. Dennis Clifton, Pharm.D.
Date Prepared:	March 18, 2008

II. General Information on Device

Proprietary Name:	Pre~Va Vaginal Lubricant
Classification Name:	lubricant, patient, vaginal, latex compatible (21 CFR 884.5300, Product Code NUC)

III. Predicate Devices

Predicate Device	510(k) control #
Pre' Vaginal Lubricant	K051436

IV. Description of Device

This product is a non-sterile, water-based personal lubricant formulated to supplement the body's own natural lubricating fluids. Pre~Va is used to lubricate vaginal tissues to facilitate entry of diagnostic or therapeutic devices including those used in fertility interventions. It is also used as a personal lubricant to supplement the body's own natural lubricating fluids and to enhance the comfort of intimate sexual activity. The formulation does not harm sperm function and has a pH and osmolarity that are physiologic ("balanced") to that of fertile cervical mucus and semen. The product is compatible with latex and polyurethane condoms. Following is the ingredient list for Pre~Va 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

V. Intended Use

- To lubricate vaginal tissues to facilitate entry of diagnostic or therapeutic devices including those used in fertility interventions. Pre~Va may be applied directly to the device or may be deposited intravaginally using the applicator, prior to the insertion of diagnostic or therapeutic devices used in fertility interventions
- As a personal lubricant Pre~Va supplements the body's own natural lubricating fluids, to moisturize, relieve friction and to enhance the ease and comfort of intimate sexual activity. Pre~Va is safe for use by couples who are trying to conceive and may be applied to vaginal or penile tissues for lubrication and moisturization purposes. It is compatible with latex and polyurethane condoms.

VI. Technological Characteristics of Device Compared to Predicate Device
All of the technological characteristics of Pre~Va are identical to the predicate device.

VII. Summary of Performance Data
The performance data of Pre~Va are identical to the predicate.

VIII. Conclusion
Pre~Va Vaginal Lubricant is safe for its intended use and substantially equivalent to the predicate device Pre' Vaginal Lubricant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2008

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

Re: K072741
Trade/Device Name: Pre-Va Vaginal Lubricant
Regulatory Class: 21 CFR 884.5300
Regulation Number: Condom
Product Code: NUC
Dated: July 1, 2008
Received: July 8, 2008

Dear Dr. Clifton:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(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 Biometric's (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,

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

Indications for Use

510(k) Number (if known): K072741

Device Name: Pre~Va Vaginal Lubricant

Indications for Use:

- To lubricate vaginal tissues to facilitate entry of diagnostic or therapeutic devices including those used in fertility interventions. Pre~Va may be applied directly to the device or may be deposited intravaginally using the applicator, prior to the insertion of diagnostic or therapeutic devices used in fertility interventions.
- As a personal lubricant Pre~Va supplements the body's own natural lubricating fluids, to moisturize, relieve friction and to enhance the ease and comfort of intimate sexual activity. Pre~Va is safe for use by couples who are trying to conceive and may be applied to vaginal or penile tissues for lubrication and moisturization purposes. It is compatible with latex and polyurethane condoms

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

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K072741

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2008

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

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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

Indications for Use

510(k) Number (if known): K072741

Device Name: Pre~Va Vaginal Lubricant

Indications for Use:

- To lubricate vaginal tissues to facilitate entry of diagnostic or therapeutic devices including those used in fertility interventions. Pre~Va may be applied directly to the device or may be deposited intravaginally using the applicator, prior to the insertion of diagnostic or therapeutic devices used in fertility interventions.
- As a personal lubricant Pre~Va supplements the body's own natural lubricating fluids, to moisturize, relieve friction and to enhance the ease and comfort of intimate sexual activity. Pre~Va is safe for use by couples who are trying to conceive and may be applied to vaginal or penile tissues for lubrication and moisturization purposes. It is compatible with latex and polyurethane condoms

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

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K072741

Page __ of ___

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

June 10, 2008

INGFERTILITY, LLC
17206 S. SPANGLE CREEK RD.
VALLEYFORD, WA 99036
ATTN: DENNIS CLIFTON

510(k) Number: K072741
Device: PRE-VA VAGINAL LUBRICANT

Extended Until: 24-JUL-2008

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

INGfertility

June 3, 2008

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

RE: K072741
Pre~Va Vaginal Lubricant – extension request

Dear Sir/Madam:

The above referenced 510(k) submission has been extended until 24-June-2008. The testing currently being conducted will not be completed by that date. We respectfully request a further extension to complete this work and submit a response.

Please contact me if you have questions or need further information.

Sincerely,

G. Dennis Clifton, Pharm.D.
Vice President

K072

INGfertility, LLC
17206 Spangle Creek Road
Valleyford, Washington 99036

Voice: 509.443.0149
Toll Free: 888.471.7333
Fax: 509.471.9638
www.ingfertility.com

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 12, 2008

INGFERTILITY, LLC
17206 S. SPANGLE CREEK RD.
VALLEYFORD, WA 99036
ATTN: DENNIS CLIFTON

510(k) Number: K072741
Device: PRE-VA VAGINAL LUBRICANT

Extended Until: 24-JUN-2008

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

INGfertility

May 5, 2008

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

FDA CDRH DMC

MAY 12 2008

Received

RE: K072741
Pre~Va Vaginal Lubricant – extension request

Dear Sir/Madam:

We have received the April 25, 2008 correspondence regarding the above referenced 510(k) submission. We will need greater than thirty days to gather the requested information. Therefore, the purpose of this letter is to officially request an extension of time to obtain the requested information and submit a response.

Please contact me if you have questions or need further information.

Sincerely,

G. Dennis Clifton, Pharm.D.
Vice President

INGfertility, LLC
17206 Spangle Creek Road
Valleyford, Washington 99036

Voice: 509.443.0149
Toll Free: 888.471.7333
Fax: 509.471.9638
www.ingfertility.com

K7

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 25 2008

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

Re: K072741
Trade Name: Pre~Va Vaginal Lubricant
Dated: March 18, 2008
Received: March 20, 2008

Dear Dr. Clifton,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require:

Biocompatibility

1. To support the biocompatibility of Pre~Va Vaginal Lubricant, (b)(4) (b)(4) (b)(4) The following testing was conducted (b)(4) : rabbit vaginal irritation, rabbit penile irritation, human skin sensitization, and slug mucosal irritation. The (b)(4) lubricant did not induce any irritation or sensitization reactions in the animals or human subjects. (b)(4) (b)(4) the results of biocompatibility testing provided for the (b)(4) are acceptable for the Pre~Va lubricant.

   However, you have not provided the results of systemic toxicity testing (b)(4) (b)(4) . This information is necessary to assess if repeated use of this product may cause absorption into the vaginal mucosal tissue and possibly cause systemic effects. Please provide the complete protocol and results of systemic toxicity testing for review.

   If you believe that systemic toxicity testing is not necessary for clearance of this lubricant, please provide justification for your decision.

2. In response to Question 5 of our AI letter dated December 21, 2007, regarding the biocompatibility of the applicator to be marketed with Pre~Va lubricant, you provided the