510(K) SUMMARY

510(k)	K131355
SUBMITTER	SASMAR, INC. 155 North Wacker Drive Chicago, IL 60606
CONTACT PERSON	John-Michael Mancini Chief Executive Officer Tel: (773) 942 0030 Fax: (773) 337 9148
MANUFACTURER	SASMAR SPRL 40-42 rue de l'Association 1000 Brussels Belgium Tel +32 2 880 8220 Fax +32 2 880 8221
PREPARATION DATE	6 November, 2013
TRADE NAME	CONCEIVE PLUS®
CLASSIFICATION NAME	Personal Lubricant
CLASSIFICATION PANEL	Condom Class II (21 CFR 884.5300)
PRODUCT CODE	PEB (lubricant, personal, gamete, fertilization, and embryo compatible)
PREDICATE DEVICE (Primary)	Pre-Va Vaginal Lubricant (K072741)
DEVICE DESCRIPTION	CONCEIVE PLUS® is non-sterile water-based personal lubricant and vaginal moisturizer that is isotonic. The device contains calcium and magnesium ions and is formulated to meet a pH range that is compatible with sperm survival and migration. CONCEIVE PLUS® supplements the body's own natural moisture and is compatible with sperm, oocytes and embryos and can be used by couples trying to conceive. The device is packaged in a plastic tube or a pre-filled applicator for intra-vaginal application.

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CONCEIVE PLUS® is formulated using Deionized Water, Hypromellose, Sodium Phosphate, Sodium dihydrogen Phosphate, Potassium Chloride, Sodium Chloride, Magnesium Chloride, Calcium Chloride, Glycerol and Methylparaben.

This device is batch lot tested for appearance, color, odor, viscosity, osmolarity, specific gravity, pH, microbial limits, endotoxin, mouse embryo assay, and human sperm survival assay.

INDICATION FOR USE

CONCEIVE PLUS® is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

CONCEIVE PLUS® is compatible with sperm, oocytes and embryos and can be used by couples trying to conceive. This product can be used in fertility interventions to facilitate entry of diagnostic and therapeutic devices into the vaginal cavity.

CONCEIVE PLUS® is compatible with natural rubber latex and polyurethane condoms. CONCEIVE PLUS® is not for use with polyisoprene condoms.

TECHNOLOGICAL CHARACTERISTICS

CONCEIVE PLUS® is a patent pending and proprietary formulation. The device has similar ingredients, similar composition and intended use to the predicate device.

Any minor differences in technological characteristics between CONCEIVE PLUS® and the predicate device do not raise new issues of safety or efficacy.

Technological Characteristics of CONCEIVE PLUS® Compared to Predicate.

Attribute	CONCEIVE PLUS®	Currently marketed, previously FDA cleared device. Pre-Va Vaginal Lubricant
510(k)	K131355	K072741
Indications for use	CONCEIVE PLUS® is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. CONCEIVE PLUS® is compatible with sperm, oocytes and embryos and can be used by couples trying to conceive. This product can be used in fertility interventions to facilitate entry of diagnostic and therapeutic devices into the vaginal cavity. CONCEIVE PLUS® is compatible with natural rubber latex and polyurethane condoms. CONCEIVE PLUS® is not for use with polyisoprene condoms.	To lubricate vaginal tissues to facilitate entry of a 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.
Method of application	Tube / Pre-filled applicator	Tube / disposable applicator
Storage instruction	36°F – 86°F	36°F – 86°F
Shelf life	2 years	2 years
Osmolarity	290 – 400 mOsm/KG	260 – 370 mOsm/KG
pH	7.0 – 7.6	7.0 – 7.4
Endotoxin (LAL)	≤ 0.5 EU/ml	≤ 0.7 EU/ml
Mouse Embryo Assay (MEA)	1-Cell MEA exposed to 10% solution for 1 hour ≥ 80% Blastocysts at 96 hours	1-Cell MEA exposed to 5% solution for 30 mins ≥ 80% Blastocysts at 96 hours
Human Sperm Survival Assay (HSSA)	Sperm motility at 2 hours exposure to 10% solution ≥ 80% control	Sperm motility at 30 min exposure to 10% solution ≥ 80% control
Ingredients	Deionized Water, Hypromellose, Sodium Phosphate, Sodium dihydrogen Phosphate, Potassium Chloride, Sodium Chloride, Magnesium Chloride, Calcium Chloride, Glycerol, Methylparaben.	Purified water, Hydroxyethylcellulose, Pluronic, Sodium Chloride, Sodium Phosphate, Carbomer, Methylparaben, Sodium Hydroxide, Arabinogalactan, Potassium Phosphate, Propylparaben.

PERFORMANCE DATA

Fertility studies performed on CONCEIVE PLUS® demonstrate that the device poses no barrier for sperm penetration or movement and does not harm motility or viability of human sperm. Bovine cervical mucus studies confirmed that the device does not hinder the ability of sperm to penetrate and migrate into cervical mucus.

Mouse Embryo Assay studies with CONCEIVE PLUS® demonstrated normal fertilization and embryo development with no suggestion of toxicity. Testing confirmed the device does not harm human sperm chromatin (DNA). Condom compatibility testing in accordance with ASTM D7661 confirmed the device is com;patible with natural latex and polyurethane condoms.

Testing confirmed that the device in both tube and applicator met all acceptance criteria for appearance, color, odor, viscosity, osmolarity, specific gravity, pH, microbial limits, endotoxin, mouse embryo assay, and human sperm survival assay throughout the entire proposed two year shelf life. Antimicrobial effectiveness testing has been conducted and the preservative system is shown to be effective.

The results of the following ISO biocompatibility tests support a determination of substantial equivalence. No adverse effects have been encountered. The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate device.

The data concludes that CONCEIVE PLUS® is substantially equivalent to its primary predicate device Pre-Va Vaginal Lubricant and is safe for use by individuals and couples trying to conceive.

Biocompatibility Test	CONCEIVE PLUS® Result
Acute Systemic Toxicity (ISO 10993-11:2006)	The device is *not systemically toxic*
Cytotoxicity (ANSI/AAMI/ISO 10993-5:2009)	The device does *not* have a Cytotoxic effect (mild reactivity).
Maximization Test For Delayed-Type Hypersensitivity (ISO 1993-5:2010)	The device does *not* elicit sensitization reactions.
Vaginal Irritation Test (ISO 1993-10:2010)	The device is *Non-Irritating*

SUMMARY

CONCEIVE PLUS® has the same intended use and basic technological characteristics as the predicate device. This lubricant is as safe and effective as the predicate and can be used by couples trying to conceive.

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

November 7, 2013

Sasmar, Inc.
% John-Michael Mancini
Chief Executive Officer
155 North Wacker Drive, Suite 4250
Chicago, IL 60606

Re: K131355
Trade/Device Name: CONCEIVE PLUS®
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: PEB
Dated: October 7, 2013
Received: October 8, 2013

Dear John-Michael Mancini,

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Benjamin R. Fisher -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K131355

Device Name

CONCEIVE PLUS®

Indications for Use *(Describe)*

Conceive Plus® is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. Conceive Plus® is compatible with sperm, oocytes, and embryos and can be used by couples trying to conceive. This product can be used in fertility interventions to facilitate entry of diagnostic and therapeutic devices into the vaginal cavity. Conceive Plus® is compatible with natural rubber latex and polyurethane condoms. Conceive Plus® is not for use with synthetic polyisoprene condoms.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Benjamin R. Fisher -S
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