December 20, 2018

Natureplex, LLC
Felicia Irons
Director of Quality
11085 Airport Road
Olive Branch, Mississippi 38654

Re: K180828
Trade/Device Name: Natureplex Warm Touch Warming Jelly
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: November 21, 2018
Received: November 23, 2018

Dear Felicia Irons:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael T. Bailey -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180828

Device Name
Natureplex Warm Touch Warming Jelly

Indications for Use *(Describe)*
Natureplex Warm Touch Warming Jelly 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. This product is compatible with natural rubber latex condoms. This product is not compatible with polyisoprene or polyurethane 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary-K180828

Company Name:	Natureplex, LLC
Company Address:	11085 Airport Road Olive Branch, MS 38654-0221
Contact Person:	Felicia Irons 901-825-8556
Summary Preparation Date:	December 17, 2018
Device Trade Name:	Natureplex Warm Touch Warming Jelly
Common Name:	Personal Lubricant
Regulation Number:	21 CFR 884.5300
Regulation Name:	Condom
Product Code:	NUC (Lubricant, Personal)
Device Class:	Class II
Predicate Device:	Sheffield's Warming LubriGel Personal Lubricant K052162

The predicate device has not been subject to a design-related recall.

Description of Device

Warm Touch Warming Jelly is a non-sterile, clear, colorless, viscous jelly for use as a personal lubricant. The device is designed to supplement the body's own natural lubrication fluids and is compatible for use with natural rubber latex condoms during intimate sexual activity. The device is not compatible with polyurethane or polyisoprene condoms.

The primary packaging for the product is a low-density polyethylene (LDPE) tube with a cap, and peel seal for safety. Each tube is secondarily packaged in a cardboard carton.

The device specifications are listed in the table below:

Parameter	Specification
Appearance	Smooth clear gel
Odor	None to slight wax scent

pH	4.0-6.0
Viscosity	60,000-155,000 cps
Total Aerobic Microbial Count (TAMC) per USP <61>	<10 cfu/g
Total Yeast and Mold Count (TYMC) per USP<61>	<10 cfu/g
Water Activity per USP <1112D>	≤0.023 aw
Absence of Pathogenic Organisms (*S. aureus, P. aeruginosa, and C. albicans*) per USP<62>	Absent

Indications for Use

Natureplex Warm Touch Warming Jelly 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. This product is compatible with natural rubber latex condoms. This product is not compatible with polyisoprene or polyurethane condoms

Predicate Device Comparison

Feature	**K1800828 Warm Touch Warming Jelly Subject Device**	**K052162 Sheffield's Warming LubriGel Personal Lubricant Predicate Device**
Indication for Use	Natureplex Warm Touch Warming Jelly 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. This product is compatible with natural rubber latex condoms. This product is not compatible with polyisoprene or polyurethane condoms	Personal lubricant for penile and vaginal use only (compatible with latex condoms)

Formulation	Propylene glycol, polyethylene glycol, hydroxypropyl cellulose, lactic acid	Propylenecol, polyethylene glycol, hydroxypropyl cellulose, lactic acid
Condom Compatibility	Natural rubber latex condoms	Natural rubber latex condoms
pH	4.0-6.0	Not known
Viscosity	60000-155000 cPs	Not known
Total Microbial	<10 cfu/g (USP <61>)	Not known
Fungal/Yeast/Mold	<10 cfu/g(USP <61>)	Not known
Absence of Pathogenic Organisms (*S. aureus, P. aeruginosa, and C. albicans*)	Absent	Not known
Shelf-Life	2 years	Not known

The subject and predicate devices have different indications for use statements; however, their intended uses are the same, i.e., lubrication during intimate sexual activity and compatibility with natural rubber latex condoms.

The subject and predicate devices have similar technological characteristics (e.g., condom compatibility, formulation ingredients, etc.); however, differences in specifications and concentrations of specific chemicals in the formulation exist.

The differences in technological characteristics described above between the subject and predicate devices do not raise different questions of safety and effectiveness. In addition, the specifications for the subject device are comparable to other devices of this type.

Performance Data

Biocompatibility:
Biocompatibility studies were performed in accordance with the 2016 FDA guidance document "Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process" and ISO 10993- 1:2009 as follows:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Vaginal Irritation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2006)

The results of this testing demonstrated that the subject lubricants are biocompatible.

Condom Compatibility:
Condom Compatibility testing was performed in accordance with ASTM D7661-10

"Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms." The results based on the recognized standard demonstrate that the product is compatible with natural rubber latex condoms. No testing was performed on polyisoprene or polyurethane condoms. Therefore, the Warm Touch Warming Jelly is labeled as not compatible with polyisoprene and polyurethane condoms.

Shelf-Life:
The shelf-life of Warm Touch Warming Jelly is 24 months from the date of production. This is based on the results of real-time stability studies that demonstrated the device can maintain its specifications over the duration of its shelf-life.

Substantial Equivalence:
The results of the performance testing described above demonstrate that the Warm Touch Warming Jelly is as safe and effective as the predicate device and supports a determination of substantial equivalence.