May 18, 2021

Nantong Health & Beyond Hygienic Products, Inc.
Michael Zhu
General Manager
No. 118, Yuxian road, North Town Street
Rugao, Jiangsu 226575
China

Re: K202667
Trade/Device Name: Personal Lubricant Jelly
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: April 5, 2021
Received: April 23, 2021

Dear Michael Zhu:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202667

Device Name
Personal Lubricant Jelly

Indications for Use *(Describe)*
Personal Lubricant 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 polyurethane condoms and 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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K202667

510(K) Summary – K202667

Prepared Date: May 13, 2021

1. Submitter's Information

Name:	NANTONG HEALTH & BEYOND HYGIENIC PRODUCTS INC.
Address:	No.118, Yuxian road, North Town Street Rugao City Jiangsu, CHINA 226575
Contact person:	Michael Zhu
Title:	General manager
E-mail:	rd@healthandbeyond.cn
Tel:	086-512-57108262

2. Device Identification

Trade/Device Name:	Personal Lubricant Jelly
Common name:	Personal Lubricant
Regulation Number:	21 CFR 884.5300
Regulation Name:	Condom
Product Code:	NUC (Lubricant, Personal)
Regulatory Class:	II

3. Predicate Device

510(K) number:	K180764
Device Name:	Trojan™ Azul Personal Lubricant (H2O Sensitive Touch Personal Lubricant)

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

4. Device Description

Personal Lubricant Jelly is a clear, slightly yellow, water-based personal lubricant that is compatible with natural rubber latex condoms. This product is not compatible with polyisoprene and polyurethane condoms. The subject lubricant contains water, hydroxyethylcellulose, glycerin, phenoxyethanol, sodium benzoate, and lactic acid. The subject lubricant is provided in two types of packages: a 2 oz. and 4 oz. polyethylene tube with a screw on top, with sealing film placed over the tube, and a 2.5 oz high density polyethylene bottle with a screw on top. The subject lubricant is a personal lubricant for over the counter (OTC) use.

Device specifications are listed in **Table 1** below:

Table 1. Device Specifications for Personal Lubricant Jelly (Subject Device)

Parameter	Specification
Appearance	Liquid or gel free from foreign and contaminating substance, no foul odor
Color	Slightly yellow
Odor	No foul odor
pH per USP<791>	4.0-5.5
Viscosity per USP<912>	900-2000 cps
Osmolality per USP<785>	450-600 mOsm/L (1:10 dilution)
Antimicrobial Effectiveness per USP<51>	Meets USP <51> acceptance criteria for Category 2 specification products
Total Microbial Count per USP<61>	TAMC <100 cfu/g
Fungal/Yeast/Mold Limits per USP<61>	TYMC <10 cfu/g
Absence of Pathogenic Organisms per USP<62> *(Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Salmonella sp., Clostridium sp., Candida albicans)*	Absent

5. Indications for use

Personal Lubricant 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 polyurethane condoms and polyisoprene condoms.

6. Comparison of Intended Use and Technological Characteristics to the Predicate Device

A comparison of the intended use and technological characteristics of the subject and predicate devices is provided in **Table 2** below:

Table 2. Subject and Predicate Device Comparison

Characteristics	Subject device	Predicate device K180764	Comparison
Manufacturer	NANTONG HEALTH & BEYOND HYGIENIC PRODUCTS INC.	Church & Dwight Co., Inc.	--
Trade name and model	Personal Lubricant Jelly	Trojan™ Azul Personal Lubricant (H2O Sensitive Touch Personal Lubricant)	--

K202667

Intended Use	Personal Lubricant 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 polyurethane condoms and polyisoprene condoms.	Trojan Azul personal lubricant (H2O sensitive touch personal lubricant) is a personal lubricant for penile and/or vaginal application, intended to lubricate and moisturize, to enhance to ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	Similar
Condom Compatibility	Natural Rubber Latex (NRL)	NRL and polyisoprene	Different
Base Type	Water	Water	Same
Primary Ingredients	Water Hydroxyethylcellulose Glycerin Phenoxyethanol Sodium Benzoate Lactic Acid	Deionized Water Glycerin Symocide pH (Phenoxyethanol, Hydroxyacetophenone, Caprylyl Glycol, Water) Hydroxyethyl-Cellulose Sodium Hyaluronate Sodium Citrate Sodium Chloride Citric Acid Sodium Hydroxide Vitamin E TPGS Veragel 200 Standardized (Aloe Barbadensis Leaf Extract)	Different
Appearance	Clear Gel	Clear Gel	Same

Color	Slightly yellow	Clear and colorless	Different
Odor	No foul odor	Characteristic odor	Different
pH	4.0-5.5 (25℃)	5.9-6.9	Different
Viscosity	900-2000 CPS (LVT#2 12 RPM, 1 min, 250 mL @ 25℃)	1500-7500	Different
Osmolality	400-650 mOsm/L (1:10 dilution)	250-550 mOsm/L	Different
Antimicrobial effectiveness	Meets USP <51> acceptance criteria for Category 2 specification products	Meets Requirement	Same
TAMC	< 100 cfu/g	< 100 cfu/g	Same
TYMC	< 10 cfu/g	<10 cfu/g	Same
Absence of pathogenic organisms	Absent	Absent	Same
Shelf life	3 years	24 months	Different

The subject and predicate devices have similar indications for use statements and have the same intended use – to provide lubrication during intimate sexual activity. The subject and predicate devices have different technological characteristics including differences in condom compatibility, ingredients, color, odor, pH, viscosity, osmolality, and shelf life. However, these differences in technological characteristics do not raise different questions of safety and effectiveness.

7. Non-Clinical Performance Data

Biocompatibility:

The biocompatibility of the subject lubricant was evaluated in accordance with the 2020 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."* The following tests were conducted:

1. Cytotoxicity (ISO 10993-5:2010 *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*)

K202667

2. Sensitization (ISO 10993-10:2010 *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization*)
3. Vaginal Irritation (ISO 10993-10:2010 *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization*)
4. Acute Systemic Toxicity (ISO 10993-11:2017 *Biological evaluation of medical devices - Part 11: Tests for systemic toxicity*)

The results of these tests demonstrated that the subject lubricant is non-cytotoxic, non-sensitizing, non-irritating, and non-systematically toxic.

Condom compatibility:

Condom Compatibility testing was conducted in accordance with *ASTM D7661-10 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms*. Test results demonstrated that the subject device is compatible with natural rubber latex condoms, but not compatible with polyurethane condoms and polyisoprene condoms.

Shelf life:

Personal Lubricant Jelly has a shelf life of 3 years based on the results of an accelerated aging stability study per ASTM F1980-16**,** *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*. The device specifications listed in **Table 1** were evaluated in the shelf-life study. The subject device met the device specifications across the shelf life duration.

8. Conclusion

The results of the testing described above demonstrate that the Personal Lubricant Jelly is as safe and effective as the predicate device and supports a determination of substantial equivalence.