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

July 30, 2015

Thai Nippon Rubber Industry Co., Ltd.
% Stuart Goldman
Senior Consultant
Emergo Group
816 Congress Avenue Suite 1400
Austin, Texas 78701

Re: K142790
Trade/Device Name: OneTouch Lubricant Gel
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: June 30, 2015
Received: July 1, 2015

Dear Stuart Goldman,

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 Industry and Consumer Education 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" (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 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 Industry and Consumer Education 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,

Joyce M. Whang -S

for Benjamin 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142790

Device Name
OneTouch™ Lubricant Gel

Indications for Use *(Describe)*
OneTouch™ Lubricant Gel 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 and polyisoprene condoms. This product is not compatible with 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)

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)*

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

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510(k) Summary

for

OneTouch™ Lubricant Gel

1. Submission Sponsor

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2. Submission Correspondent

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Email: project.management@emergogroup.com

3. Date Prepared

July 30, 2015

4. Device Identification

Trade/Proprietary Name:	OneTouch™ Lubricant Gel
Common/Usual Name:	Lubricant, Personal
Classification Name:	Condom
Classification Regulation:	§884.5300
Product Code:	NUC
Device Class:	Class II
Classification Panel:	Obstetrics/Gynecology

5. Legally Marketed Predicate Device(s)

Global Protection Corp. [ONE® Oasis (K110691)]
Ansell Healthcare Products [LifeStyles® Smooth™ 2-in-I Massage & Lubricant (K122476)]

6. Device Description

One Touch™ Lubricant Gels by Thai Nippon Rubber Industry Company, Ltd. ("TNR") are a line of personal lubricants, 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. These lubricants are compatible with natural rubber latex and

polyisoprene condoms, and are not a contraceptive and do not contain a spermicide. One Touch™ Lubricant Gels are made available in three (3) different versions: One Touch™ Plain, One Touch™ Flavored and One Touch™ Colored, and come packaged in either single-use disposable application film/foil sachets, or in multiple application polyethylene tubes with a flip-top closure. OneTouch™ Lubricant Gels use hydroxyethyl cellulose and refined glycerin as the lubricating agent, with the methyl paraben, propyl paraben and cremophor acting as the antiseptic and preservative additives.

7. Indication for Use Statement

OneTouch™ Lubricant Gel 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 and polyisoprene condoms. This product is not compatible with polyurethane condoms.

8. Substantial Equivalence Discussion

TNR has chosen two predicate devices in the 510(k) submission for their OneTouch™ Lubricant Gel, those being ONE® Oasis by Global Protection Corp. (K110691) and LifeStyles® Smooth™ 2-in-1 Massage & Lubricant by Ansell Healthcare Products (K122476).

The following table 5-1 compares OneTouch™ Lubricant Gels to the predicate devices with respect to intended use, technological characteristics and principles of operation, thus providing more detailed information regarding the basis for the determination of substantial equivalence in this 510(k) submission.

Table 5-1
OneTouch™ Lubricant Gels vs. Predicate Devices - Similarities and Differences

Device	OneTouch™ Lubricant Gel	ONE® Oasis	LifeStyles® Smooth™ 2-in-1 Massage & Lubricant	Differences
510(k):	Pending	K110691	K122476	-
Manufacturer:	Thai Nippon Rubber Industry Company, Ltd.	Global Protection Corp.	Ansell Healthcare Products	-
Product Code:	NUC	NUC	NUC	Same. The subject and predicate devices share the same FDA product code.
Regulation:	§884.5300	§884.5300	§884.5300	Same. The subject and predicate devices share the same FDA regulation number.
Class:	II	II	II	Same. The subject and predicate devices share the same FDA device classification.
Prescription or OTC Use:	OTC	OTC	OTC	Same. The subject and predicate

				devices are sold OTC.
Intended Use:	OTC personal lubricant.	OTC personal lubricant.	OTC personal lubricant.	Same. The subject and predicate devices are sold OTC and intended be used as a personal lubricant.
Indications for Use:	OneTouch™ Lubricant Gel 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 lubricant. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.	ONE® Oasis 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, polyisoprene, and polyurethane condoms.	Indications for Use: LifeStyles® Smooth™ 2-in-I Massage & Lubricant 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, polyurethane, and polyisoprene condoms.	Similar. The subject and predicate devices have virtually the same indications for use; any minor wording differences between them are insignificant to their intended use and do not affect the safety or efficacy.
Mode of Operation (Lubricating Agent):	hydroxyethyl cellulose	hydroxyethyl cellulose	hydroxyethyl cellulose	Similar. The subject and predicate devices use hydroxyethyl cellulose as the main lubricating agent in their product formulation; overall ingredient % may vary.
Water Based Lubricant:	Yes	Yes	Yes	Same. The subject and predicate devices are water-based personal lubricants.
Sterile:	No	No	No	Same. The subject and predicate devices are not provided sterile or

				intended to be sterilized by the user.
Body Location Target Area:	for penile and/or vaginal application	for penile and/or vaginal application	for penile and/or vaginal application	Same. The subject and predicate devices are for penile and/or vaginal application.
Single Use:	Yes	Yes	Yes	Same. The subject and predicate devices are applied, as needed, to the target area.
Packaging:	Single use film/foil sachets and multiple use tubes.	Multiple use tubes.	Multiple use plastic pump dispenser.	Similar. The subject and predicate devices use somewhat different sizes and shapes for their OTC packaging, but these differences are minor and have no impact on the safety or efficacy of the personal lubricant.
Shelf-life:	3 years	1 year	3 years	Similar. The subject and predicate devices have the same or similar shelf-life for their OTC packaging, but these differences are minor and have no impact on the safety or efficacy of the personal lubricant.
Biocompatibility Testing Performed:	Yes ISO 10993-1 (-5, -10, -11)	Yes ISO 10993-1 (-5, -10, -11)	Yes ISO 10993-1 (-5, -10, -11)	Same. The subject and predicate devices have undergone biocompatibility in accordance with the applicable parts of ISO 10993-1.
Condom Compatibility Testing Performed:	Yes ASTM D7661-10	Yes ASTM D7661-10	Yes ASTM D7661-10	Same. The subject and predicate devices have been tested for condom compatibility in accordance with ASTM D7661-10.
Microbiological	Yes	Not known	Yes	Same. The subject

Examination of Non-sterile Products Testing:	USP 37 (<61>/<62>)		USP	and one of the predicate devices (K122476) have been tested for microorganism contamination in accordance with the applicable parts of the USP.

9. Non-Clinical Performance Data

As part of demonstrating the safety and effectiveness of OneTouch™ Lubricant Gel and in showing substantial equivalence to the predicate devices, TNR completed a number of tests on their device to prove this. OneTouch™ Lubricant Gel meets all the requirements for overall design, biocompatibility, condom compatibility, microbial contamination, package shelf-life and device risk, which confirms that the outputs meets the design inputs and specifications for the device.

OneTouch™ Lubricant Gel passed all the testing in accordance with national and international standards shown below to support substantial equivalence to the predicate devices.

- Biocompatibility Testing (Per ISO 10993-1)
- Condom Compatibility Testing (Per ASTM D7661)
- Total Aerobic Microbial Counts (Per USP 37 <61>/<62>)
- Total Combined Yeast and Mold Counts (Per USP 37 <61>/<62>)
- Package Shelf-Life (Per ASTM F1980)
- Device Risk Analysis (Per ISO 14971)

10. Clinical Performance Data

There was no human clinical testing required to support OneTouch™ Lubricant Gel as the indications for use is equivalent to the predicate devices. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the intended use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of OneTouch™ Lubricant Gel to the predicate devices.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the subject device has the same intended use and the same technological characteristics as the previously cleared device, or has the same intended use and different technological characteristics, but it can be demonstrated that the new device is substantially equivalent to the predicate device, and that the new device does not raise any questions regarding its safety and effectiveness when compared to the predicate device.

OneTouch™ Lubricant Gel and the predicate devices that are the subject of this 510(k) submission, all function as 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 to supplement the body's natural lubricant, and are all compatible with natural

rubber latex, polyisoprene, and polyurethane condoms, but are not a contraceptive and do not contain a spermicide.

Therefore, based on the substantial equivalence analysis described above, OneTouch™ Lubricant Gel, as designed, developed, manufactured, packaged and tested by TNR, is determined to be substantially equivalent to ONE® Oasis (K110691) and LifeStyles® Smooth™ 2-in-1 Massage & Lubricant (K122476) personal lubricants regulated by the FDA as a Class II medical device under Product Code NUC and §884.5300.