October 21, 2022

Thai Nippon Rubber Industry Public Company Limited
Tossaporn Nilkhamhang
Chief Technical Officer
789/139 Pinthong Industrial Estate Nongkham
Sriracha, Chonburi 20230
Thailand

Re: K220273
Trade/Device Name: Onetouch™ Non-paraben Lubricant Gel
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: September 5, 2022
Received: September 23, 2022

Dear Tossaporn Nilkhamhang:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K220273

Device Name
Onetouch™ Non-paraben Lubricant Gel

Indications for Use *(Describe)*
Onetouch™ Non-paraben Lubricant Gel is a personal lubricant, for penile, vaginal and/or anal application, intended to moisturize and lubricate, 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)*

510(k) Summary
Onetouch™ Non-paraben Lubricant Gel

1. Submitter Information

Applicant: Thai Nippon Rubber Industry Public Company Limited
Contact: Tossaporn Nilkhamhang
Address: 789/139 Moo 1 Pinthong Industrial Estate Nongkham
Sriracha Chonburi 20110 Thailand
Phone: (+66-38-317999)

2. Correspondent Information

Company: Regulatory Insight
Contact: Kevin Walls
Phone: (720) 962-5412
Email: kevin@reginsight.com

3. Device Information

Device Name:	Onetouch™ Non-paraben Lubricant Gel
Common Name:	Personal Lubricant
Regulation Number:	21 CFR 884.5300
Regulation Name:	Condom
Product Code:	NUC (lubricant, personal)
Regulatory Class:	Class II

4. Predicate Device Information

Device Name:	OneTouch™ Lubricant Gel
510(k) Number:	K142790
Manufacturer:	Thai Nippon Rubber Industry Public Company Limited

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

5. Device Description

Onetouch™ Non-paraben Lubricant Gel is a non-sterile, water-based, over-the-counter use personal lubricant that is intended for penile, vaginal and/or anal application, to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. Onetouch™ Non-paraben Lubricant Gel is compatible with natural rubber latex and polyisoprene condoms. The product is not compatible with polyurethane condoms.

Onetouch™ Non-paraben Lubricant Gel has the following eight flavor and color versions:

1. Natural Color, No Flavor
2. Natural Color, Cucumber Flavor
3. Natural Color, Mixfruit Flavor
4. Pink Color, Strawberry Flavor
5. Natural Color, Strawberry Flavor
6. Natural Color, Vanilla Flavor
7. Natural Color, Mentha Piperita (Peppermint) Flavor
8. Natural Color, Aloe Vera Flavor

The formulations of all versions consist of purified water, hydroxyethyl cellulose, refined glycerin, propane-1,3-diol, sodium benzoate, and PEG-40 hydrogenated castor oil. Specific versions of the device include flavors or a pink colorant, as shown in the list above.

Onetouch™ Non-paraben Lubricant Gel is packaged in 75ml LDPE plastic tubes or 5 ml PE layered aluminum foil sachets. Sachets and tubes are secondarily packaged in cartons.

Device specifications are listed in Table 1 below:

Table 1: Device Specifications for Onetouch™ Non-paraben Lubricant Gel

Property	Specification
Appearance	A clear medium viscous gel, free of foreign matter
Color	Colorless (all natural color versions) Pink (Pink Color, Strawberry Flavor version)
Odor	Odorless (Natural Color, No Flavor version) Cucumber (Natural Color, Cucumber Flavor version) Mixfruit (Natural Color, Mixfruit Flavor version) Strawberry (Pink Color, Strawberry Flavor version) Strawberry (Natural Color, Strawberry Flavor version) Vanilla (Natural Color, Vanilla Flavor version) Mentha Piperita (Natural Color, Mentha Piperita (Peppermint) Flavor version) Aloe Vera (Natural Color, Aloe Vera Flavor version)
Viscosity (USP<912>	9,500 -16,000 cps
pH at 25°C (USP<791>)	5.5 – 6.5
Osmolality (USP<785>)	300-600 mOsm/kg (1:8 dilution)
Antimicrobial Effectiveness (USP<51>)	Bacteria: NLT 2.0 log reduction from the initial count at 14 days, and no increase from 14 days count at 28 days; Yeasts/Molds: No increase from the initial calculated count at 14 and 28 days.
Total Aerobic Microbial Count (TAMC, per USP <61>)	<100 cfu/g
Total Yeast and Mold Count (TYMC, per USP <61>)	<10 cfu/g
Presence of Pathogenic Organisms (*Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans, Escherichia coli, Salmonella,* per USP<62>)	Absent

6. Indications for Use

Onetouch™ Non-paraben Lubricant Gel is a personal lubricant, for penile, vaginal and/or anal application, intended to moisturize and lubricate, 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.

7. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below compares the intended use and technological characteristics of the subject and predicate device:

Table 2: Comparator Table for Subject and Predicate Device

	Onetouch™ Non-paraben Lubricant Gel Subject Device	**OneTouch ™ Lubricant Gel K142790 Predicate Device**	**Comparison**
Indications for Use	Onetouch™ Non-paraben Lubricant Gel is a personal lubricant, for penile, vaginal and/or anal application, intended to moisturize and lubricate, 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.	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.	The indications for use for the subject and predicate devices are not identical, as the subject device is for anal, vaginal, and penile use, while the predicate device is only for vaginal and penile use. The addition of anal use for the subject device does not represent a new intended use, which is the same for both the subject and predicate devices (e.g., to provide lubrication during intimate sexual activity).
Base type	Water-based	Water-based	Same
Not a contraceptive or Spermicide	Yes	Yes	Same
Primary ingredients	- Purified Water - Hydroxyethyl cellulose -Refined Glycerin -Propane-1,3-diol -Sodium Benzoate - PEG-40 Hydrogenated Castor Oil - Flavor (specific to device versions) - Pink colorant (specific to colored device version)	- Purified Water - Hydroxyethyl cellulose -Refined Glycerin -Methyl 4-Hydroxybenzoate -Propyl 4-Hydroxybenzoate -PEG-40 Hydrogenated Castor Oil - Flavor (specific to device versions) - Pink colorant (specific to colored device version)	**Different:** The subject and predicate devices have different formulations. These differences do not raise different questions of safety and effectiveness (S&E).

Rx/OTC	OTC	OTC	Same
Sterile	No	No	Same
Appearance	Clear medium viscous gel, free of foreign matter, natural color or pink color depending on device version.	Clear medium viscous gel, free of foreign matter, natural color or pink color depending on device version.	Same
Odor	Dependent on version (odorless, cucumber, mixfruit, strawberry, vanilla, mentha piperita, or aloe vera)	Odorless	**Different:** The subject device includes versions with and without odors, while as versions of the predicate device are stated to be odorless. This difference does not raise different questions of S&E.
Flavored Versions	Yes – 7 versions	Yes – 1 version	**Different:** Both include flavored versions; however, the subject device includes more flavored versions. Differences in flavored versions does not raise different questions of S&E.
Viscosity	9,500 -16,000 cps	8,000 –20,000cps	Similar
Osmolality	300-600 mOsm/kg (1:8 dilution)	≤1,200 mOsm/kg	**Different:** The osmolality specification is not the same as the predicate device. This difference does not raise a different question of S&E.
pH	5.5 - 6.5	5.5 - 6.5	Same
Microbial Limits	Total aerobic microbial count: <100 cfu/g Total yeast/mold count: <10 cfu/g Absence of pathogens (*Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, Salmonella*)	Total aerobic microbial count: <100 cfu/g Total yeast/mold count: <10 cfu/g Absence of pathogens (*Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, Salmonella*)	Same
Antimicrobial Effectiveness	Yes	Yes	Same
Condom Compatibility	Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms.	Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms.	Same
Shelf-Life	12 months	Three years	**Different:** The subject device has a shorter shelf-life than the predicate device. This

			difference does not raise a different question of S&E.

As stated in the table, the indications for use for the subject and predicate devices are not identical, as the subject device is for anal, vaginal, and penile use, while the predicate device is only for vaginal and penile use. The addition of anal use for the subject device does not represent a new intended use, which is the same for both the subject and predicate devices (e.g., to provide lubrication during intimate sexual activity).

The subject and predicate device have different technological characteristics, including formulations, odors, flavors, osmolality specification, and shelf-life duration. The different technological characteristics identified do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility testing was performed 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 testing was conducted:

- Cytotoxicity (ISO 10993-5:2009)
- Guinea Pig Maximization Sensitization (ISO 10993-10:2010)
- Vaginal Irritation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The results of this testing demonstrate that the subject lubricant is non-cytotoxic, non-irritating, non-sensitizing, and not systemically toxic.

Shelf-Life

The subject device has a shelf-life of 12 months based on the results of real-time and accelerated aging testing. All specifications for the subject lubricant listed in Table 1 were met throughout the shelf-life study in lubricant packaged in tubes and sachets.

Condom Compatibility

The compatibility of Onetouch™ Non-paraben Lubricant Gel with condoms was evaluated in accordance with ASTM D7661-10(R) 2017 *Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms*. The results of testing showed compatibility of the lubricant with natural rubber latex and polyisoprene condoms. The results also showed that the device is not compatible with polyurethane condoms.

10. Conclusion

The results of the testing described above demonstrate that Onetouch™ Non-paraben Lubricant Gel is as safe and effective as the predicate device and supports a determination of substantial equivalence.