



March 7, 2023

RB Health (US) LLC
Lisa Burns
Sr. Manager Regulatory Affairs
399 Interpace Parkway
Parsippany, NJ 07054

Re: K213892
Trade/Device Name: Grosz Warming Liquid, Grosz Play Tingling, Grosz KY Yours & Mine
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: January 31, 2023
Received: February 3, 2023

Dear Lisa Burns:

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,


Michael T. Bailey -S

For

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

Indications for Use

510(k) Number (if known)
K213892

Device Name
Grosz Warming Liquid, Grosz Play Tingling, Grosz KY Yours & Mine

Indications for Use (Describe)

Grosz Warming Liquid 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. This product is compatible with natural rubber latex, polyisoprene and polyurethane condoms.

Grosz Play Tingling 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. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Grosz KY Yours & Mine 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. 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
K213892
Grosz Warming Liquid, Grosz Play Tingling, and Grosz KY Yours & Mine

510(k) Owner: RB Health (US)
Street Address: 399 Interpace Parkway, Parsippany, NJ 07054-0224
Contact Person: Lisa Burns
Contact Numbers: 862-325-0012
Summary Preparation Date: March 1, 2023
Trade Name: Grosz Warming Liquid, Grosz Play Tingling, Grosz KY Yours & Mine
Common Name: Personal Lubricant
Device Classification: Regulation Name: Condom
Regulation Number: 21 CFR 884.5300
Product Code: NUC (lubricant, personal)
Device Class: Class II
Predicate Device: Swiss Navy Premium Silicone Lubricant and Swiss Navy Premium Water-Based Lubricant
510(k) Number: K150153
Manufacturer: Package Solutions LLC
Product Code: NUC
Device Class: Class II

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

Device Description:

Grosz Warming Liquid is a non-sterile, silicone-based personal lubricant compatible with natural rubber latex, polyisoprene, and polyurethane condoms. Its formulation consists of Dimethicone and Sensate. Grosz Warming Liquid is packaged in a 30 mL high density polyethylene bottle (HDPE) mono layer and topped with a polypropylene cap. The bottle is then packaged in a carton. Grosz Warming Liquid is a personal lubricant for over-the-counter (OTC) use.

Grosz Play Tingling is a non-sterile, water-based personal lubricant compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. Its formulation consists of Water, Propylene Glycol, Carbomer, Xanthan Gum, Sensate, Benzoic Acid, Sodium Saccharin, and Sodium Hydroxide. Grosz Play Tingling is packaged in a 50 mL HDPE bottle and topped with a polypropylene cap. The bottle is then packaged in a carton. Grosz Play Tingling is a personal lubricant for OTC use.

Grosz KY Yours & Mine are two personal lubricants with the same formulations and specifications as Grosz Warming Liquid and Grosz Play Tingling, respectively, packaged together and compatible with natural rubber latex and polyisoprene condoms. Grosz KY Yours & Mine is not compatible with polyurethane condoms when used as intended. Grosz KY Yours and Grosz KY Mine are individual lubricants separately packaged in a 44 mL polyethylene terephthalate

bottles and topped with a polypropylene cap and packaged together in a carton. Grosz KY Yours & Mine are for OTC use.

The device specifications are listed in the tables below:

Table 1 Grosz Warming Liquid and Grosz KY Yours

Property	Specification
Appearance	Liquid
Color	Clear, Colorless
Odor	Odorless
Viscosity per <USP 912>	70-110 cPs
Antimicrobial effectiveness per 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 method equivalent to USP<61>	< 100 cfu/g
Total yeast and mold count (TYMC) per method equivalent to USP<61>	< 10 cfu/g
Presence of Pathogens per EP 8.0 Section: 2.6.13	Specification
<i>Pseudomonas aeruginosa</i>	Absent/g
<i>Staphylococcus aureus</i>	Absent/g
<i>Escherichia coli</i>	Absent/g
<i>Candida albicans</i>	Absent/g

Table 2 Grosz Play Tingling and Grosz KY Mine

Property	Specification
Appearance	Gel
Color	Transparent, Colorless
Odor	Very slightly acidic, no objectionable odor
Viscosity per USP <912>	3,400 – 10,000 cPs
pH per USP <791>	3.5 – 4.5
Osmolality per USP <785>	883-1,200 mOsm/kg
Antimicrobial effectiveness per method equivalent to USP<51>	Bacteria: NLT 3.0 log reduction from the initial count at 7 days, and no increase from 7 days' count at 28 days; Yeasts/Molds: 2.0 log reduction from the initial count at 14 days, and no increase from the 14 days' count at 28 days.
Total aerobic microbial count (TAMC) per method equivalent to USP<61>	< 100 cfu/g

Total yeast and mold count (TYMC) per method equivalent to USP<61>	< 10 cfu/g
Presence of Pathogens per method equivalent to USP<62>	Specification
<i>Pseudomonas aeruginosa</i>	Absent/g
<i>Staphylococcus aureus</i>	Absent/g
<i>Escherichia coli</i>	Absent/g
<i>Candida albicans</i>	Absent/g

Indications for Use Statements:

Grosz Warming Liquid 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. This product is compatible with natural rubber latex, polyisoprene and polyurethane condoms.

Grosz Play Tingling 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. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Grosz KY Yours & Mine 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. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Comparison of Intended Use and Technological Characteristics to the Predicate Device:

In the table below, the predicate for Grosz Warming Liquid and Grosz Yours is the Swiss Navy Premium Silicone Lubricant, while the predicate for Grosz Play Tingling and Grosz KY Mine is the Swiss Navy Premium Water Based Lubricant.

Feature	Grosz Warming Liquid K213892	Grosz Play Tingling K213892	Grosz KY Yours & Mine K213892	Swiss Navy Premium [Silicone Lubricant and Water-Based Lubricant] K150153	Comments
Indications for Use	Grosz Warming Liquid 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. This product is compatible with natural rubber latex, polyisoprene and polyurethane condoms.	Grosz Play Tingling 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. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	Grosz KY Yours & Mine 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. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	The Swiss Navy Premium Lubricants are 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 products are compatible with natural rubber latex and polyisoprene condoms. These products are not compatible with polyurethane condoms.	The indications for use statements for the subject and predicate devices are not identical, as the subject devices are also indicated for anal use and have differences in condom compatibility. These differences do not represent a new intended use as both the subject and predicate devices are intended to provide lubrication to an orifice with or without use of compatible condoms.
Base Type	Silicone	Water	Grosz KY Yours: Silicone Grosz KY Mine: Water	Silicone Lubricant: Silicone Water-Based Lubricant: Water	Same: The subject devices and their respective predicate device have the same base type.
Primary ingredients	Dimethicone, Sensate	Water, Propylene Glycol, Carbomer, Xanthan Gum, Sensate, Benzoic Acid, Sodium Saccharin, Sodium Hydroxide	Grosz KY Yours: Dimethicone, Sensate Grosz KY Mine: Water, Propylene Glycol, Carbomer, Xanthan Gum, Sensate, Benzoic Acid, Sodium Saccharin, Sodium Hydroxide	Not available	Differences in formulations is not known between Grosz Warming Liquid/Grosz KY Yours and the Swiss Navy Premium Silicone Lubricant or between Grosz Play Tingling/Grosz KY Yours and the Swiss Navy Premium Water Based Lubricant. Differences in formulations do not raise different questions of safety

					and effectiveness (S&E).
Over the counter use	Yes	Yes	Yes	Yes	Same: The subject devices and their respective predicate device are for OTC use.
Sterile	No	No	No	No	Same: The subject devices and their respective predicate device are non-sterile.
Condom Compatibility	Compatible with natural rubber latex and polyisoprene condoms and polyurethane condoms.	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.	These products are compatible with natural rubber latex and polyisoprene condoms. These products are not compatible with polyurethane condoms.	Different: Condom compatibility differs between the subject devices and their respective predicate device. Differences in condom compatibility does not raise different questions of S&E.
Biocompatibility Tested	Yes	Yes	Yes	Yes	Same: The subject devices and their respective predicate device were tested and shown to be biocompatible.
Antimicrobial Tested	Yes	Yes	Yes	Unknown	Differences in antimicrobial testing is not known between Grosz Warming Liquid/Grosz KY Yours and the Swiss Navy Premium Silicone Lubricant or between Grosz Play Tingling/Grosz KY Yours and the Swiss Navy Premium Water Based Lubricant. Differences in antimicrobial testing do not raise different questions of safety and effectiveness (S&E).
Microbial Tested (Total aerobic microbial count, total yeast and mold count, absence of pathogens)	Yes	Yes	Yes	Yes	Same: The subject devices and their respective predicate device completed this testing.
pH Tested	No	Yes	Grosz KY Yours: No	Silicone Lubricant: No	Same: The subject devices and their respective predicate

			Grosz KY Mine: Yes	Water-Based Lubricant: Yes	device are the same regarding testing for this parameter.
Osmolality Tested	No	Yes	Grosz KY Yours: No Grosz KY Mine: Yes	Silicone Lubricant: No Water-Based Lubricant: Yes	Same: The subject devices and their respective predicate device are the same regarding testing for this parameter.
Viscosity Tested	Yes	Yes	Yes	Yes	Same: The subject devices and their respective predicate device are the same regarding testing for this parameter.

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 devices have different technological characteristics. For example, different formulations. The different technological characteristics identified in the table do not raise different questions of safety and effectiveness.

Summary of Performance Data:

Biocompatibility

Biocompatibility studies, including cytotoxicity, sensitization, vaginal irritation, and acute systemic toxicity testing were 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”*, as follows:

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

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

Shelf-Life:

The subject devices in this submission have the following shelf-life durations:

- Grosz Warming Liquid – 15 months
- Grosz Play Tingling – 2 years
- Grosz KY Yours – 2 years
- Grosz KY Mine – 2 years

The shelf-life durations for the subject devices are based on the results of accelerated aging and real-time testing for Grosz Warming Liquid and Grosz KY Yours and accelerated aging testing for Grosz Play Tingling and Grosz KY Mine. All specifications for Grosz Warming Liquid/Grosz KY Yours and Grosz Play Tingling/Grosz KY Mine listed in Tables 1 and 2, respectively, were met throughout the shelf-life duration.

Condom Compatibility:

The compatibility of the subject devices was evaluated in accordance with ASTM D7661-10 *“Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms.”* Grosz Warming Liquid was determined to be compatible with natural rubber latex, polyisoprene and polyurethane condoms. Grosz Play Tingling was determined to be compatible with natural rubber latex and polyisoprene condoms, and not compatible with polyurethane condoms. Grosz KY Yours & Mine when used together as intended, was determined to be compatible with natural rubber latex and polyisoprene condoms, and not compatible with polyurethane condoms.

Conclusion:

The results of the performance testing described above demonstrate that Grosz Warming Liquid, Grosz Play Tingling, and Grosz KY Yours & Mine are as safe and effective as their respective predicate devices and support a determination of substantial equivalence.