April 14, 2020

Bath Concept Cosmetics (Dongguan) Co., Ltd
% Wei Zhang, Ph.D., RAC
Regulatory Manager
RGLM Consulting LLC
3302 171 St Pl SE
Bathell, WA 98012

Re: K191654
Trade/Device Name: SILICONE Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: March 10, 2020
Received: March 13, 2020

Dear Wei Zhang:

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.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191654

Device Name
SILICONE Personal Lubricant

Indications for Use *(Describe)*
SILICONE Personal 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 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.

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

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510(k) Summary – K191654

SILICONE Personal Lubricant

A. General Information

Submitter	Bath Concept Cosmetics (Dongguan) Co., Ltd No.2, Dushang Industrial Zone, DaFen, WanJiang District, Dongguan city, Guangdong, China
Contact Person (Preparer)	Wei Zhang, PhD RAC RGLM consulting LLC Regulatory Manager Tel: 425-236-4274 Email: wei@rglm-fda.com
Date prepared	April 13, 2020

B. Device

Propriety Name	SILICONE Personal Lubricant
Common Name	Personal Lubricant
Product Code	NUC (Lubricant, Personal)
Regulatory Class	II
Regulation Number	21 CFR §884.5300
Regulation Name	Condom

C. Predicate Device

Name	ONE® SILICONE Personal Lubricant
Owner	ONE®, 12 Channel Street Boston, MA 02210
510(k) number	K110690

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

D. Description of the Device

SILICONE Personal Lubricant is a non-sterile, clear and odorless silicone-based personal lubricant for use during intimate sexual activity. This device is compatible with natural rubber latex and polyisoprene condoms. This device is not compatible with polyurethane condoms. Its formulation consists of dimethicone and dimethiconol. The product is packed into a 3.38 oz (100 mL) bottle. Device specifications are listed in Table 1 below:

Table 1. Subject Device Specifications

Property	Specification
Appearance	Clear Gel
Color	Colorless
Odor	Odorless
Viscosity (@ 25°C) per USP <912>	300-700cps
Total aerobic microbial count (TAMC) per USP <61>	< 10 CFU/g
Total yeast and mold count (TYMC) per USP <61>	< 10 CFU/g
Absence of Pathogens per USP <62>	
Escherichia coli	Absence
Pseudomonas aeruginosa	Absence
Staphylococcus aureus	Absence
Salmonella Enterica subsp.	Absence
Candida albicans	Absence
Clostridium sporogenes	Absence
Bile-tolerant Gram-negative Bacteria	Absence

E. Indications for Use

SILICONE Personal 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 and polyisoprene condoms. This product is not compatible with polyurethane condoms.

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

	Subject Device	**Predicate Device**
Product	SILICONE Personal Lubricant	ONE® SILICONE Personal Lubricant
Sponsor	Bath Concept Cosmetics (Dongguan) Co., Ltd	ONE®
510(k) number	K191654	K110690
Regulation No.	21 CFR §884.5300	21 CFR §884.5300
Product Code	NUC	NUC
Class	II	II
Intended use	SILICONE Personal Lubricant is an over-the-counter personal lubricant.	ONE® SILICONE Personal Lubricant is an over-the-counter personal lubricant.
Indications for Use	SILICONE Personal 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	ONE® SILICONE Personal 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

	latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	with natural rubber latex, polyisoprene, and polyurethane condoms.
OTC use?	Yes	Yes
Primary ingredients	Dimethicone Dimethiconol	Dimethicone Dimethiconol
Targeted population	Adult	Adult
Appearance	Clear	Clear
Color	Colorless	Colorless
Odor	No Odor	No Odor
Viscosity (25°C)	300-700cps	300-400 cps
Total aerobic microbial count (TAMC)	< 10 CFU/g	< 10 CFU/g
Total yeast and mold count (TYMC)	< 10 CFU/g	< 10 CFU/g
Absence of pathogenic organisms	Absence	Not provided
Application site	Penile and/or vaginal	Penile and/or vaginal
Condom Compatibility	Natural Rubber Latex and Polyisoprene	Natural Rubber Latex, Polyurethlane, and Polyisoprene
Sterility	Non-sterile	Non-sterile
Biocompatibility Tests	Comply with ISO 10993 biocompatibility evaluation	Comply with ISO 10993 biocompatibility evaluation

Shelf Life	1 year & 6 months (18 months)	1 year (12 months)

The subject product and the predicate device have similar indications for use statements and have the same Intended Use.

The subject and predicate device have different technological characteristics, including different shelf-life and condom compatibility. The differences in technological characteristics described above between the subject and predicate device do not raise different questions of safety and effectiveness.

G. Summary of non-clinical performance testing:

Shelf life

SILICONE Personal Lubricant has a one-year-and-six-month (18 months) shelf life based on the results of an accelerated aging study. The results of the shelf life study demonstrated that the subject device met all device specifications at baseline and throughout the proposed shelf life.

Condom Compatibility

The compatibility of the SILICONE Personal Lubricant with male condoms was tested in accordance with ASTM D7661-10 *Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms*. Condom compatibility testing was performed with three different brands of natural rubber latex, one brand of polyisoprene, and one brand of polyurethane condoms. The results indicate that SILICONE Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms and is not compatible with polyurethane condoms.

Biocompatibility

The biocompatibility evaluation for the SILICONE Personal Lubricant was conducted in accordance with the FDA Guidance “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process’", June 2016, and

International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA.

The evaluation included the following tests:

- 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 lubricant is non-cytotoxic, non-irritating, non-sensitizing, and not systemically toxic.

H. Conclusions

The results of the performance testing described above demonstrate that the SILICONE personal lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.