April 25, 2019

LFBeauty (Thailand) Limited
% Shelley Shen, Ph.D.
Consultant
PharmEng Technology
23 Lesmill Road
North York, M3B 3P6 Ontario
CANADA

Re: K182100
Trade/Device Name: Smile Makers Personal Lubricants (Smile Makers Little Light Liquid, Smile Makers Stay Silky Serum, and Smile Makers Generous Gel)
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: March 19, 2019
Received: March 21, 2019

Dear Shelley Shen:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Benjamin R. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182100

Device Name
Smile Makers Personal Lubricants (Smile Makers Little Light Liquid, Smile Makers Stay Silky Serum, and Smile Makers Generous Gel)

Indications for Use *(Describe)*

Smile Makers Personal Lubricants are water-based personal lubricants for penile and/or vaginal application, intended to lubricate and moisturize, 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
K182100
Smile Makers Personal Lubricants

I. Submitter

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Date Prepared
April 24, 2019

II. Subject Device

Trade Names
Smile Makers Personal Lubricants:

- Smile Makers Little Light Liquid
- Smile Makers Stay Silky Serum
- Smile Makers Generous Gel

Common Name
Personal Lubricant

Classification
Regulation Name: Condom
Regulation Number: 21 CFR 884.5300

Regulatory Class: II
Product Code: NUC (lubricant, personal)

III. Predicate Device

BioFilm, Inc. – Astroglide Sensual Strawberry (K140590)

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

IV. Device Description

Smile Makers personal lubricants are water-based personal lubricants. There are three formulations, Generous Gel, Stay Silky Serum, and Little Light Liquid, that contain the same ingredients, and only differ in amounts of specific ingredients. Ingredients of the lubricants include the following: water (aqua), glycerin, propylene glycol, methyl propanediol, carbomer, sodium benzoate, sodium hydroxide, and dipotassium glycyprizate. They are compatible with natural rubber latex and polyisoprene condoms, but are not compatible with polyurethane condoms. They are provided non-sterile.

The product is packaged in 30 ml transparent plastic bottles made of acrylonitrile styrene and polyethylene terephthalate. The bottle contains a pump dispenser made of polypropylene and the cap is made of an aluminum coated low density polyethylene. It is for over-the-counter use.

The specifications for Smile Makers personal lubricants are listed in **Table 1** below:

Table 1: Smile Makers Personal Lubricant Specifications

Parameter	**Specification (Test Method)**
Appearance & Color	Clear gel, viscous, no visible foreign matter
Odor	Characteristic odor
Osmolality (10% (w/w) dilution with water)	299 – 449 mOsm/kg
pH (at 25 °C)	4.90 – 5.50
Viscosity	56,000 – 84,000 cps (Generous Gel) 6,200 – 10,000 cps (Stay Silky Serum) 3,700 – 5,600 cps (Little Light Liquid)
Total Aerobic Microbial Count (USP <61>)	<10 cfu/g
Total Yeast & Mold Count (USP <61>)	<10 cfu/g
Antimicrobial Effectiveness (USP <51>)	
Escherichia coli, Pseudomonas	No less than a 2.0 log reduction from

aeruginosa, Staphylococcus aureus	the initial count at 14 days, and no increase from the 14 days' count at 28 days
Candida albicans, A. brasiliensis	No increase from the initial count at 14 and 28 days
Absence of Pathogenic Organisms (USP <62>)	
Staphylococcus aureus	Absent
Pseudomonas aeruginosa	Absent
Candida albicans	Absent

V. Indications for Use Statement

Smile Makers Personal Lubricants are water-based personal lubricants for penile and/or vaginal application, intended to lubricate and moisturize, 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.

VI. Comparison of Intended Use and Technological Characteristics

Table 2: Technological Characteristics of Smile Makers Personal Lubricants Compared to Predicate

	Smile Makers Personal Lubricants K182100 Subject Device	**Astroglide Sensual Strawberry K140590 Predicate Device**
Sponsor	LFBeauty (Thailand) Ltd.	BioFilm, Inc.
Indication for Use	Smile Makers personal lubricants are water-based personal lubricants for penile and/or vaginal application, intended to lubricate and moisturize, 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.	Astroglide Sensual Strawberry 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.
Water-based	Yes	Yes

Appearance	Clear gel, viscous, no visible foreign matter	Clear, colorless
Primary Ingredients	Water, Glycerin, Propylene Glycol, Methyl propanediol, Carbomer, Sodium Benzoate, Sodium Hydroxide, Dipotassium Glycyprizate	Not known
Provided Non-Sterile	Yes	Yes
Condom Compatibility	Natural rubber latex, Polyisoprene	Natural rubber latex, Polyisoprene, Polyurethane
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested	Yes	Yes

The subject and predicate devices have the same indications for use statements with the exception of condom compatibility. The subject device is compatible with natural rubber latex and polyisoprene but not compatible with polyurethane condoms. The predicate device is compatible with natural rubber latex, polyisoprene, and polyurethane condoms. These differences do not impact the intended uses of these devices, which are the same (i.e., lubrication during intimate sexual activity).

As noted in the table above, the subject and predicate device have different formulations and condom compatibilities. The differences in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness.

VII. Performance Data

Biocompatibility Testing

Biocompatibility studies were performed in accordance with the 2016 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" and ISO 10993-1: 2009 as follows:

- Cytotoxicity (ISO 10993-5: 2009)
- Guinea Pig Maximization Sensitization Test (ISO 10993-10: 2010)
- Vaginal Irritation (ISO10993-10: 2010)
- Acute Systemic Toxicity (ISO 10993-11: 2017)

The results demonstrate that the subject lubricants are non-cytotoxic, non-

sensitizing, non-irritating, and non-systemically toxic.

Condom Compatibility

The compatibility of the subject devices with natural rubber latex, polyisoprene and polyurethane condoms was evaluated in accordance with ASTM D7661-10 “Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms” and was determined to be compatible with natural rubber latex and polyisoprene condoms. The subject device was determined not to be compatible with polyurethane condoms.

Shelf-life

The Smile Makers Personal Lubricant has a one-year shelf-life based on the results of a real-time aging study. Testing demonstrated that the device met specifications for parameters shown in Table 1.

VIII. Conclusion

The results of performance testing described above demonstrate that the Smile Makers Personal Lubricants are as safe and effective as the predicate device and support a determination of substantial equivalence.