September 25, 2019

Desert Harvest, Inc
% Abhishek Gurnani
Partner
Amin Talati Wasserman, LLP
100 S. Wacker Drive, Suite 2000
Chicago, IL 60606

Re: K190323
Trade/Device Name: Aloe Glide Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: August 23, 2019
Received: August 26, 2019

Dear Abhishek Gurnani:

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,

Sharon M. Andrews
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)*
K190323

Device Name
Aloe Glide Lubricant

Indications for Use *(Describe)*
Aloe Glide 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.

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510(k) Summary
Aloe Glide Lubricant – K190323

This summary uses the format provided in 21 CFR 807.92:

(a)(1) **Submitter/Owner:** Desert Harvest, Inc.
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NC 27278 Phone: 919-245-
1853

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Summary Prepared: September 24, 2019

(a)(2) **Trade Name:** Aloe Glide Lubricant

Common Name: Personal Lubricant

Regulation Number: 21 CFR 884.5300

Regulatory Name: Condom

Regulatory Class: Class II

Product Code: NUC (lubricant, personal)

(a)(3) **Identification of Predicate Device:** Aloe Cadabra Personal Lubricant (K124044).

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

(a)(4) **Device Description:** Aloe Glide Lubricant is a personal lubricant that is non-sterile, water-based, and provides lubrication during intimate sexual activity. This device is compatible with natural rubber latex and polyisoprene condoms, and is not compatible with polyurethane condoms. Its formulation consists of water, xanthan gum, licorice and marshmallow extract, aloe barbadensis leaf extract, potassium sorbate, citric acid, and natapres. Aloe Glide is packaged in 2, 4, and 8 fl. oz bottles composed of polyethylene terephthalate (PET). Aloe Glide lubricant is a personal lubricant for over-the-counter (OTC) use.

Device specifications are listed in Table 1 below.

Table 1: Subject Device Specifications

Property	**Specification**
Appearance	Clear and transparent
Odor	Characteristic
Viscosity	10,000 - 15,000 cps
Osmolality	300 – 400 mOsm/kg
pH at 25 °C	4.5 – 5.8
Total Aerobic Microbial Count (USP <61>)	<100 cfu/g
Total Yeast & Mold Count (USP <61>)	<10 cfu/g
	<100 cfu/g
Absence of Pathogenic Organisms (USP <62>)	
Pseudomonas aeruginosa	Absent
Staphylococcus aureus	Absent
Candida albicans	Absent
Escherichia coli, Salmonella, Clostridium Species	Absent
Antimicrobial Effectiveness (USP<51>)	
Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus,	NLT a 2.0 log reduction from initial count at 14 days and no increase from the 14 day count at 28 days
Candida albicans, Aspergillus niger	No increase from the initial calculated count at 14 and 28 days

(a)(5) **Indications for Use Statement:** Aloe Glide 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.

The subject and predicate device have the same intended use.

(a)(6) **Comparison of Technological Characteristics**

Table 2. Technological Characteristics of Aloe Glide and Compared to the Predicate

	K190323	**K124044**
	Subject Device	**Predicate**
Sponsor	Desert Harvest, Inc.	Seven Oaks Ranch, Inc.
Regulation Number Product Code Device Class	844.5300 NUC II	844.5300 NUC II
Indications for Use	Aloe Glide 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.	Aloe Cadabra® Lubricant and Aloe Cadabra® Flavored/Scented 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. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.
Physical Features	Clear liquid	Not known
Water-based	Yes	No (Aloe-based)
Primary Ingredients	Water Xanthan Gum Natapres*	Aloe Extract
Sterile	No	No
Condom Compatibility	Natural Rubber Latex Polyisoprene	Natural Rubber Latex Polyisoprene
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested	Yes	Yes

*Natapres contains glycerin, leuconostoc/radish, root ferment filtrate, lonicera japonica (honeysuckle) flower extract, lonicera caprifolium (honeysuckle) extract, populus tremuloides bark extract, and gluconolactone

The subject and predicate devices have the same indications for use statements. As noted in the table above, the subject and predicate device have different formulations. The differences in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness.

(b) Summary of Performance Data

Biocompatibility: Aloe Glide has undergone biocompatibility testing including cytotoxicity based on alternate testing comparable to ISO 10993-5: 2009, human repeat insult patch testing (sensitization and irritation), and acute systemic toxicity testing per ISO 10993-11:2017. The testing found that Aloe Glide is 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: Aloe Glide has a 1-year shelf life in accordance with the results of an accelerated aging stability study. Results from testing demonstrated that the device can maintain its specifications (as shown in Table 1) over the duration of its shelf life.

Conclusion: The results of the performance testing described above demonstrate that the Aloe Glide is as safe and effective as the predicate device and supports a determination of substantial equivalence