April 19, 2024

Laclede, Inc.
Rajvinder Atwal
Quality Assurance
2103 E. University Dr.
Rancho Dominguez, California 90220

Re: K240508
Trade/Device Name: Salivea Dry Mouth Moisturizing Gel (Dry Mouth Moisturizing Gel)
Regulatory Class: Unclassified
Product Code: LFD
Dated: February 21, 2024
Received: February 21, 2024

Dear Rajvinder Atwal:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

FDA Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

Salivea Dry Mouth Moisturizing Gel (Dry Mouth Moisturizing Gel)

Indications for Use *(Describe)*

Relieve symptoms of dry mouth, refresh, moisturize, soothes oral irritation, and lubricate oral dryness.

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 – K240508

Submission By: Laclede, Inc.
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Contact Name: Stephen Pellico
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Correspondent Name: Rajvinder Atwal
Email: ratwal@laclede.com

Date 510(k) Summary Prepared: 4/18/2024

Trade Name/Device Name: SALIVEA DRY MOUTH MOISTURIZING GEL

Regulation Number: Unclassified
Regulation Name: Saliva, Artificial
Product Code: LFD

Primary Predicate Device:
Oral Balance Gel, Laclede, Inc., K061331

Reference Predicate Device:
Oral 7 Moisturizing Gel, J.C.E.C Company Inc., K142549
Salivea Dry Mouth Mouthwash, Salivea Dry Mouth MouthSpray, Laclede, Inc., K180680
Biotene Oral Balance Gel, GSKCH, K123731

Device Description:
Salivea Dry Mouth Moisturizing Gel are specially formulated artificial saliva which contain moisturizers, humectants and salivary enzymes that collectively have lubricating, moisturizing, soothing and refreshing properties to relieve and treat the symptoms of dry mouth.
The Salivea Dry Mouth Moisturizing Gel is supplied in 1 oz tube and sample foil pack.

Indications for use:
Relieve symptoms of dry mouth, refresh, moisturize, soothes oral irritation, and lubricate oral dryness.

Substantial Equivalence:
Salivea products have the same intended use, technical characteristics and physiological purpose. Any minor variations in formula/composition are to allow proper dispensing and use of product and do not affect the function, indications, or equivalency of proposed product.

Product	**Salivea Dry Mouth Gel**	**Oral Balance Gel (K061331)** *Primary Predicate*	**Oral7 Moisturizing Gel (K142549)** *Reference Predicate*	**Biotene Oral Balance Gel (K123731)** *Reference Predicate*	**Salivea Dry Mouth Mouthwash, Salivea Dry Mouth MouthSpray (K180680)** *Reference*
Intended Use	Symptomatic Treatment of xerostomia	Symptomatic Treatment of xerostomia	Symptomatic Treatment of xerostomia	Symptomatic Treatment of xerostomia	Symptomatic Treatment of xerostomia
Method of Use	Ready to use Gel	Ready to use Gel	Ready to use Gel	Ready to use Gel	Ready to use Gel
Applications per Day	As needed	As needed	As needed	As needed	As needed
Disease State	Xerostomia	Xerostomia	Xerostomia	Xerostomia	Xerostomia
Area of Use	Oral Cavity	Oral Cavity	Oral Cavity	Oral Cavity	Oral Cavity
Type of Product	Gel	Gel	Gel	Gel	Gel
Presentation	Non-Sterile, tube	Non-Sterile, tube	Non-Sterile, tube	Non-Sterile, tube	Non-Sterile, bottle

Discussion and conclusions from the Nonclinical Testing:
Biocompatibility was established generally following 10993-1. The Mucosal irritation, Sensitization (maximization), Acute Oral toxicity.
Stability studies demonstrated that the formulations are safe and stable.
Comparative physical properties testing with predicate device was performed. The results were comparable. Physical testing includes pH, Viscosity and Specific gravity.

No clinical tests were performed.

Conclusion:
Salivea Dry Mouth Moisturizing Gel has the same intended use and similar technological properties as primary and reference predicate devices. Salivea Dry Mouth Moisturizing Gel and Oral Balance Gel are similar formulation. Minor differences between Salivea Dry Mouth Moisturizing Gel and Oral Balance Gel formula do not affect device safety and effectiveness. All ingredients in the Salivea Dry Mouth Moisturizing Gel are commonly used for their intended functions.
The performance data demonstrate that the subject device is substantially equivalent to the predicate device in terms of safety and effectiveness.
Given the similarities in chemical composition, available delivery forms and physical properties between subject and primary predicate devices, Salivea Dry Mouth Moisturizing Gel are safe and effective as the primary and reference predicate devices.