Laclede, Inc.
Rajvinder Atwal
QA Manager
2103 E. University Dr.
Rancho Dominguez, California 90220

October 11, 2018

Re: K180680
Trade/Device Name: Salivea Dry Mouth Mouthwash, Salivea Dry Mouth Mouthspray
Regulatory Class: Unclassified
Product Code: LFD
Dated: September 5, 2018
Received: September 6, 2018

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 (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,

Mary S. Runner -S3

forTina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Salivea Dry Mouth Mouthwash and Salivea Dry Mouth MouthSpray.

Indications for Use *(Describe)*

Relieve symptoms of dry mouth, refresh, moisturize, clean and sooth oral irritation, and 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.

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

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510 (k) Summary

Submission By: Laclede, Inc.
Address: 2103 E. University Drive
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Telephone: 310-605-4280
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Contact Name: Michael A. Pellico, President
Email: mpellico@laclede.com

Date 510(k) Summary Prepared: September 13, 2018

Trade Name/Device Name: SALIVEA DRY MOUTH MOUTHWASH
SALIVEA DRY MOUTH MOUTHSPRAY
Regulation Number: Unclassified
Regulation Name: Saliva, Artificial
Product Code: LFD

Primary Predicate Device:
BIOTENE MOISTURIZING MOUTHSPRAY, GSKCH, K103745
BIOTENE DRY MOUTH MOUTHWASH, GSKCH, K101477

Reference Predicate Device:
Oral 7 Moisturizing Spray and Mouthwash, J.C.E.C Company Inc., K142549
Oral Balance Gel, Laclede, Inc., K061331

Device Description:
Salivea Dry Mouth Mouthwash and Salivea Dry Mouth Mouthspray are specially formulated saliva substitute 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 MouthSpray is supplied in non-pressurized pump action spray white Polyethylene terephthalate bottle.
The Salivea Dry Mouth Mouthwash is supplied in white Polyethylene terephthalate bottle.

Indications for Use:
Relieve symptoms of dry mouth, refresh, moisturize, clean and sooth oral irritation, and 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 Mouthwash**	**Biotene Dry Mouth Mouthwash (K101477)**	**Salivea Dry Mouth MouthSpray**	**Biotene Moisturizing Mouthspray (K103745)**
Method of Use	Ready to use liquid	Ready to use liquid	Ready to use spray	Ready to use spray
Applications per Day	As needed	As needed	As needed	As needed
Disease State	Xerostomia	Xerostomia	Xerostomia	Xerostomia
Area of Use	Oral Cavity	Oral Cavity	Oral Cavity	Oral Cavity
Type of Product	Liquid	Liquid	Liquid	Liquid
Indications of Use	Supports Saliva's Natural Defense, Refresh Breath, moisturizes, gently cleans and soothes Dry Oral Irritations.	Relieves the symptoms of dry mouth, refresh, moisturize, clean, soothe oral irritation and lubricate oral dryness.	Relieve symptoms of Dry Mouth, instantly moisturizes & hydrates dry tissue, refreshes breath & soothes oral irritation.	Relieves the symptoms of dry mouth, refresh, moisturize, clean, soothe oral irritation and lubricate oral dryness.
Presentation	Non-Sterile, PET bottle	Non-Sterile, PET bottle	Non-Sterile, PET bottle	Non-Sterile, PET bottle

Discussion and conclusions from the Nonclinical Testing:
Biocompatibility was established through testing generally following ISO 10993, and includes Mucosal Irritation, Sensitization, and Oral toxicity testing. The results met the acceptance criteria of testing.

- Mucosal irritation (ANSI/ADA/ISO993-10)
- Sensitization (M&K, GPMT / ISO993-10)
- Oral toxicity (ANSI/ADA/ISO10993-5)

Physical testing includes pH, Viscosity and Specific gravity. Comparative physical properties testing with predicate device was performed and results were comparable.
Real time stability testing on physical properties i.e., Appearance, pH, viscosity and specific gravity were examined and met acceptance criteria.

Conclusion:
The subject Salivea Products has same materials (i.e., moisturizers, humectants and salivary enzymes) as the primary predicate devices. All ingredients in the Salivea products are commonly used for their intended functions. Salivea products have the same intended use and the same technological properties as primary and reference predicate devices. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.