November 21, 2019

OraLabs, Inc.
Teresa Purdue
Vice President of Quality
18685 East Plaza Drive
Parker, Colorado 80134

Re: K181839
Trade/Device Name: CVS Health Dry Mouth Spray, OraLabs Dry Mouth Spray
Regulatory Class: Unclassified
Product Code: LFD
Dated: August 20, 2019
Received: August 23, 2019

Dear Teresa Purdue:

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,

Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181839

Device Name
OraLabs Dry Mouth Pocket Spray

Indications for Use *(Describe)*
Use as needed for instant relief. OraLabs Dry Mouth Pocket Spray helps maintain the oral environment and helps provide protection against dry mouth symptoms.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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

1. Purpose of the 510(k) Notice

OraLabs requests this 510(k) as it is a new device.

There are no prior submissions for OraLabs Dry Mouth Pocket Spray, or from manufacturer OraLabs for a Dry Mouth Spray.

OraLabs initially submitted documentation in July 2018 and was assigned number K181839. Additional correspondence was submitted in January 2019 and April 2019.

2. Submitter's Information – Name, Address, Telephone Number, Contact Person and Date Prepared

OraLabs, Inc.
Gary Schlatter, CEO
18685 East Plaza Drive
Parker, CO 80134
Phone:(303) 783-9499, Extension 3202
Fax: (303) 783-5759
www.oralabs.com

This revised summary was prepared on 07/19/19 and any questions shall be addressed to:

Teresa Purdue
Vice President of Quality
18685 East Plaza Drive
Parker, CO 80134
Phone:(303) 783-9499, Extension 3249
Fax: (303) 783-5759
teresap@oralabs.com
www.oralabs.com

3. Device Name

- Proprietary name – Dry Mouth Spray
- Common Name of Device – Saliva, artificial
- Classification Name – Unclassified
- Classification Product Code – LFD
- Review Panel – Dental Device Panel

  To my knowledge, the Food and Drug Administration has not classified this device.

4. Devices to Which Substantial Equivalence is Claimed:

OraLabs claims equivalence to Biotene® Moisturizing Mouth Spray, 510(k) Number K123731.

Trade Name	Biotene® Dry Mouth Spray
Common Name	Oral Spray
Classification Name	Saliva, Artificial
Regulatory Classification	Unclassified (pre-amendment)
Product Code	LFD
Review Panel	Dental Devices Panel
510(k) Number	K123731
Submitter	GlaxoSmithKline Consumer Healthcare

5. Device Description

OraLabs Dry Mouth Pocket Spray is a specially formulated water soluble artificial saliva substitute with a pH between 5.20 to 7.20 for use at home in the oral cavity. OraLabs manufactures the products in a 0.25 FL OZ polyethylene bottle with a non-aerosol pump.

The formula contains water, moisturizers, thickeners/binders, buffers, flavor, sweetener and preservatives. The combination of ingredients collectively provides moisturizing, lubricating, soothing, and refreshing properties.

OraLabs uses a Natural Mint Blend (PE-116) that is recognized as safe (GRAS) on the FEMA/GRAS list.

OraLabs owns the formula, manufacture, label and packaging of this product.

6. Performance Data

The testing OraLabs selected to perform on OraLabs Dry Mouth Pocket Spray was to objectively prove substantial equivalence in safety and effectiveness of the proposed device to the declared predicate.

OraLabs Dry Mouth Pocket Spray is equivalent to Biotene based on performance testing of visual, sensory, pH, viscosity, moisture deabsorption and biocompatability.

The results from these tests demonstrate that OraLabs Dry Mouth Pocket Spray is substantially equivalent.

OraLabs Dry Mouth Pocket Spray is substantially equivalent based on performance testing of stability, biocompatibility, anti-bacterial activity, efficacy of preservative, and elemental impurity testing. Biocompatibility testing for Biotene and OraLabs Dry Mouth Pocket Spray exhibited the same result on L929 Direct Contact Cytotoxicity Test. These results were contributed to the presence of the Surfactant Preservatives – Cetylpyridinium Chloride and Sodium Benzoate.

The proposed medical device, OraLabs Dry Mouth Pocket Spray, is demonstrated to be substantially equivalent to the predicate device, Biotene Moisturizing Mouth Spray.

7. **Comparison Statements**

OraLabs Dry Mouth Pocket Spray is substantially equivalent to Biotene® Moisturizing Mouth Spray.

They utilize the same fundamental scientific technology (a mixture of water, moisturizers, thickening/binding agents, buffering agents, sweeteners, flavor, and preservatives).

OraLabs Dry Mouth Pocket Spray is packaged in a smaller size than the Biotene® Moisturizing Mouth Spray, volume of 0.25 FL OZ vs. 1.5 FL OZ.

See next page for a Comparison Table.

Trade Name	**Predicate Device** Biotene Moisturizing Mouth Spray	**Proposed Device** OraLabs Dry Mouth Pocket Spray
510(k) Number	K123731	K181839
Classification Name	Artificial Saliva	Artificial Saliva
Product Code	LFD	LFD
Classification	Unclassified	Unclassified
Disease State	Xerostomia (Dry Mouth)	Xerostomia (Dry Mouth)
Intended Use		
Indications for Use	Soothing Moisturization. Immediate symptom relief that lasts for up to four hours. Helps keep mouth fresh.	Use as needed for instant relief. OraLabs Dry Mouth Pocket Spray helps maintain the oral environment and helps provide protection against dry mouth symptoms.
Dosage Form	Oral Spray	Oral Spray
Dosage (Per Use)		
Method of Use	Spray	Spray
Area of Use	Oral cavity	Oral Cavity
Applications/day	Up to 5 times daily	As needed for relief of dry mouth symptoms.
Prescription/OTC	OTC	OTC
Environment of Use	Home	Home
Solvent	Water	Water
Humectants/Moisturizers	Glycerin	Glycerin
Sweeteners/Humectants	Xylitol, Sodium Saccharin	Xylitol, Sodium Saccharin
Thickeners/Binders	VP/VA Copolymer Xanthan Gum	VP/VA Copolymer Xanthan Gum
Surfactant Preservatives	Cetylpyridinium Chloride Sodium Benzoate Methylparaben Propylparaben	Cetylpyridinium Chloride, Sodium Benzoate
Flavor	Mint Flavor	Mint Flavor
Area of Use	Oral Cavity	Oral Cavity
Disease State	Xerostomia (Dry Mouth)	Xerostomia (Dry Mouth)
Appearance	Cloudy, semi-viscous	Cloudy, semi-viscous
pH	6.02, 6.11	5.2 – 7.2
Viscosity	7700 mPa*s; 7820 mPa*s	5120 mPa*s
Moisture Deabsorption	8.16%	9.97%
Solubility	Water Soluble	Water Soluble
Packaging Unit	1.5 FL OZ	0.25 FL OZ

Packaging Material - Bottle	White polyethylene terephthalate (PET)	Clear polyethylene terephthalate (PET)
Packaging Material - Cap	Polypropylene	Polypropylene
Prescription/OTC	OTC	OTC
Sterility	Non-sterile	Non-Sterile
Shelf-Life	36 months	24 months

Table A – Comparison of Predicate Device to Formula SPY DMS

8. Discussion of Differences

- Size and color of container

  OraLabs designed the OraLabs Dry Mouth Pocket Spray to be a pocket spray size that consumers can carry with them. The size of 0.25 fl oz (7.5 ml) is smaller than Biotene's 1.5 fl oz (44.3 ml). OraLabs used a clear plastic bottle instead of a white bottle like the predicate device, Biotene.

- Preservatives

  OraLabs uses two preservatives that the predicate device, Biotene has in their formula, Cetylpyridinium Chloride and Sodium Benzoate. Biotene adds methylparaben and propylparaben. OraLabs intentially opted to omit the parabens due to published literature on the use of parabens in cosmetic and OTC drug products. Performance testing (Stability) demonstrated that Cetylpyridinium Chloride and Sodium Benzoate are adequate to support a 24 month expiration date.

- Expiration date

  The predicate device, Biotene, applies a 36 month expiration date. OraLabs stability protocol supports a 24 month expiration date.

9. Bench Testing

OraLabs Dry Mouth Pocket Spray tested favorably to the predicate device on appearance and sensory properties, pH, viscosity, and moisture absorption.

Stability studies indicate an expiration date of 24 months compared to Biotene's 36 months. USP<51> testing shows the preservatives OraLabs added to OraLabs Dry Mouth Pocket Spray are acceptable for the expiration date.

An elemental impurity test was performed on OraLabs Dry Mouth Pocket Spray with acceptable results.

Biocompatibility Test Results

OraLabs conducted biocompatibility testing as listed in **Use of International Standard ISO 10993-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".**

OraLabs found the predicate device, Biotene Dry Mouth Moisturizing Spray, received identical readings for the cytotoxicity testing. As stated in Section 6, Performance Data, in this 510(k) Summary, these results were attributed to the presence of the Surfactant Preservatives – Cetylpyridinium Chloride and Sodium Benzoate.

Biological Effect	Result
Cytotoxicity	OraLabs - Fail
Sensitization	OraLabs - Pass
Irritation or Intracutaneous Reactivity	OraLabs - Pass
Cytotoxicity	Biotene - Fail

Biocompatibility results show the OraLabs Dry Mouth Pocket Spray to be as safe as the predicate product to use to relieve dry mouth symptoms.

10. Stability

OraLabs performed accelerated stability according to ICH requirements. OraLabs Dry Mouth Pocket Spray was filled into individual spray bottles and sealed with the pump assembly. The product was placed into a stability chamber at 40°C/75% Relative Humidity (40_75).

The product was tested at Baseline, 3 months, and 6 months for analytical, microbial, and organoleptic properties.

Total Aerobic Count, Yeasts & Molds, pH, and organoleptic properties maintained an acceptable result at each stage of testing.

Accelerated testing did not significantly alter the pH and the preservatives added to the OraLabs Dry Mouth Pocket Spray were acceptable as no growth was found on Total Aerobic Count and Yeasts & Molds.

These results support OraLabs applying a 24 month expiration date.

11. Conclusion

OraLabs Dry Mouth Pocket Spray is substantially equivalent to Biotene Moisturizing Mouth Spray as it has the same intended use and the same fundamental scientific technology as the legally marketed predicate device, Biotene Moisturizing Mouth Spray.

This is demonstrated by comparing the ingredients, and the purpose of each ingredient, in the OraLabs Dry Mouth Pocket Spray and Biotene.

OraLabs Dry Mouth Pocket Spray contains water, moisturizers, thickeners/binders, buffers, flavor, sweetener and preservatives. The combination of ingredients collectively provides moisturizing, lubricating, soothing, and refreshing properties.

Performance testing and biocompatibility assessment further show substantial equivalence.