September 3, 2021

Oxy2plus, LLC
Chun Lin
Co-Founder
4120 Rosemead Blvd
Rosemead, California 91770

Re: K202689
Trade/Device Name: Dentilube Spray
Regulatory Class: Unclassified
Product Code: LFD
Dated: June 28, 2021
Received: July 7, 2021

Dear Chun Lin:

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,

Michael E. Adjodha, M.ChE.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202689

Device Name
Dentilube dry mouth spray

Indications for Use *(Describe)*
Dentilube dry mouth spray is indicated for the symptomatic relief from the effects of chronic or temporary xerostomia (dry mouth), mouth discomfort, mouth odors and other oral symptoms associated with dry mouth.

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 (K202689)

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. SUBMITTER INFORMATION

Name:	Oxy2plus, LLC
Address:	4120 Rosemead Blvd Rosemead, CA 91770
Contact person:	Chun Nan Lin, DDS, MS
Telephone:	626-286-7800
FAX:	626-286-7600
Email:	oxy2plus@outlook.com

Date Summary Prepared:	June 26, 2021

2. DEVICE NAME

Device Name:	Dentilube dry mouth spray
Trade or Proprietary Name:	Dentilube dry mouth spray
Common or Usual Name:	Saliva, Artificial Classification
Name:	Saliva, Artificial
Product Code:	LFD
Classification:	Unclassified
Panel:	Dental

3. IDENTIFICATION OF EQUIVALENCE (Predicate Device):

BIO-X HEALTHCARE S.A.	*BioXtra*® Moisturizing Gel (K072306)

4. DEVICE DESCRIPTION

Dentilube dry mouth spray is a viscous pink electrolyte-containing solution that is designed to mimic the compositions and actions of saliva to moisturize, lubricate, and refresh the mouth. It provides a lubricating and moisturizing coating inside the mouth, thereby relieving symptoms of dry mouth.

The product is supplied in 50mL or 100 mL PET bottles.

5. STATEMENT OF INTENDED USE

Dentilube dry mouth spray is indicated for the symptomatic relief from the effects of chronic or temporary xerostomia (dry mouth), mouth discomfort, mouth odors and other oral symptoms associated with dry mouth.

6. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS

Characteristics of the device compared to the predicate device
Substantial Equivalence Comparison Chart

Attributes	**Subject Device**	**Predicate Device**	**Comparison**
Product	Dentilube dry mouth spray	BioXtra® Moisturizing Gel	-
Manufacturer	Oxy2plus, LLC	Bio-X Healthcare S.A.	-
510(K) #	K202689	K072306	-
Product Code	LFD	LFD	*Same*
Regulation	Pre-Amendment	Pre-Amendment	*Same*
Class	Unclassified	Unclassified	*Same*
Review Panel	Dental	Dental	*Same*
Indications for Use	*Dentilube dry mouth spray* is indicated for the symptomatic relief from the effects of chronic or temporary xerostomia (dry mouth), mouth discomfort, mouth odors and other oral symptoms associated with dry mouth.	*BioXtra*® is indicated for the symptomatic relief from the effects of chronic or temporary xerostomia (dry mouth), mouth discomfort, mouth odors and other oral symptoms associated with dry mouth.	*Same; both are indicated for relief of symptoms of xerostomia (dry mouth).*

Conditions of Use			
Dosage Form	Oral spray	Oral spray	*Same*
Area of Use	Oral cavity	Oral cavity	*Same*
Disease State	Xerostomia	Xerostomia	*Same*
Method of Use	Ready to use gel spray	Ready to use gel spray	*Same*
Application per Day	As needed	As needed	*Same*
Packaging	50 mL and 100 mL in PET bottle with spray head	50 mL in PET bottle with spray head	
Area of Use	Oral cavity	Oral cavity	*Same*
Environment of Use	Home and Clinic	Home and Clinic	*Same*

Mode of Action	Moisturizing and lubricating oral dryness	Moisturizing and lubricating oral dryness	*Same*
Type of Product	Liquid solution	Liquid solution	*Same*
Presentation	Non-sterile	Non-sterile	*same*
Rx/OTC	OTC	Rx/OTC	*The subject device is OTC only*
Composition			
Solvent	Purified water	Purified water	*same*
Buffers	Dipotassium hydrogen phosphate Potassium dihydrogen phosphate	Potassium phosphate, dibasic Sodium Chloride	*Similar. These different buffering agents are generally recognized as safe (GRAS) and provide similar pH levels for the both devices.*
Humectants/ Thickeners	Sodium carboxymethyl-cellulose	Hydroxyethyl cellulose Polyacrylic acid Sodium polyacrylate Hydrogenated starch hydrolysates (HSH)	*Similar. These different thickener agents are generally recognized as safe (GRAS) and provide similar viscosity and moisture-retaining quality for both devices.*
Preservatives	Methyl P-hydroxybenzoate (Methylparaben)	Sodium methylparaben Sodium propylparaben Sodium benzoate Potassium sorbate Citric acid monohydrate Lactoperoxidase (Hydrogen-peroxide oxidoreductase)	*Similar. These preservative agents are generally recognized as safe (GRAS) by the USFDA and are used for maintaining and extending shelf life.*
Colorant	FD&C Red 40 Dye (2%)	None	*Colorant is not used in the predicate device*
Sweeteners	Sorbitol	Sorbitol Xylitol Sodium Saccharin	*Similar. The predicate has more sweeteners. Both devices use sorbitol to balance the solution and to provide a denser solution.*

Electrolytes		Calcium chloride, anhydrous Magnesium Chloride, anhydrous Potassium Chloride Sodium fluoride		Calcium chloride, dihydrate Magnesium chloride, hexahydrate Potassium Chloride Sodium monofluoro-phosphate		*Similar. Both devices contain electrolytes similar to those found in natural saliva.*

The subject device, *Dentilube dry mouth spray*, and the predicate device have the same indications and method of use. They also share many common conditions of use. Further, both employ the same fundamental scientific technology (a formulation of water, humectants or moisturizers, thickening/binding agents, buffering agents, sweeteners, flavor, surfactants and preservatives).

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Physical Properties (Non-Clinical Performance)						
Flavors		Lemon / Mint		Mint		
Appearance		Clear Viscous Liquid		Clear Viscous Liquid		*Same*
Color		Reddish Pink		Light Straw		*Different color does not affect use*
pH		6.35		6.82		*Similar. Both subject and predicate devices have pH values near that of natural saliva (5.3 - 7.8)*
Solubility		Water Soluble		Water Soluble		*Same*
Viscosity @25ºC [RVT Spindle #5@10rpm]		3500 cps (3.5 Pa-s)		2900 cps (2.9 Pa-s)		*Similar. The values are greater viscosity of natural saliva (0.0078 Pa-s).*
Specific gravity (SPG)		1.02		1.05		*Similar. The values are not significantly different when compared to the SPG of the saliva (1.000-1.010).*

Sterility		Non-sterile		Non-sterile		*Same*
Shelf Life		2 years		2 years		*Same*
Biocompatibility		Conforms with ISO 10993-1 • cytotoxicity • sensitization • irritation		Conforms with ISO 10993-1 • cytotoxicity • sensitization • irritation		*Same*

Dentilube dry mouth spray has been tested for shelf-life/stability, which provides for a 24-month shelf life, same as the primary predicate device. Biocompatibility assessments has been done in accordance with ISO 10993 for cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10), and irritation (ISO 10993-10) and has been shown to be safe for the intended use. No other clinical tests were performed other than a Use Study for this submission.

8. DISCUSSION AND CONCLUSION

Based on the comparison of intended use and technical characteristics, as well as non-clinical performance testing, we conclude that *Dentilube dry mouth spray* is substantially equivalent to the predicate device.