August 22, 2023

GuruNanda LLC
Chetan Patel
Director, Formulation Development and Regulatory Affairs
6645 Caballero Blvd.
Buena Park, California 90620

Re: K231205
Trade/Device Name: GuruNanda Dry Mouth Oral Rinse and GuruNanda Dry Mouth Oral Spray
Regulatory Class: Unclassified
Product Code: LFD
Dated: April 27, 2023
Received: April 27, 2023

Dear Chetan Patel:

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,

FDA Bobak Shirmohammadi -S

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

Submission Number *(if known)*

N/A

Device Name

GuruNanda Dry Mouth Oral Rinse and GuruNanda Dry Mouth Oral Spray

Indications for Use *(Describe)*

The GuruNanda Dry Mouth Oral Rinse and GuruNanda Dry Mouth Oral Spray are intended to relieve the symptoms of dry mouth, refresh, moisturize, clean, soothe 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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K231205 - 510(k) Summary

510(k) Owner:
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Contact Person:
Chetan Patel
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Establishment Registration Number: 3014468707
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E-Mail: chetan@gurunanda.com

Date: July 6, 2023

Common/Usual Names:

Common Name	Common / Classification Name
Dry Mouth Oral Rinse	Saliva, Artificial
Dry Mouth Oral Spray	Saliva, Artificial

Classification Name: Saliva, Artificial

Product Code: LFD

Identification of a Legally Marketed Predicate Device:
Biotene Dry Mouth Oral Rinse and Biotene Moisturizing Mouth Spray (K123731).

General Description

The GuruNanda Dry Mouth Oral Rinse and GuruNanda Dry Mouth Oral Spray are specifically formulated as an artificial saliva substitute with water, moisturizers, humectants, sweeteners, and flavors that collectively have lubricating, moisturizing, soothing, and refreshing properties to help relieve and manage the symptoms of dry mouth (xerostomia).

Indications for Use:

The GuruNanda Dry Mouth Oral Rinse and GuruNanda Dry Mouth Oral Spray are intended to relieve the symptoms of dry mouth, refresh, moisturize, clean, soothe oral irritation, and lubricate oral dryness.

Indications for Use Discussion:

The only difference between the subject device (GuruNanda Dry Mouth Oral Rinse and GuruNanda Dry Mouth Oral Spray) and the predicate device is in the name.

Technological Characteristics

The proposed and predicate devices are similar in design and packaging. Any difference in the chemical compositions between the subject device and predicate device are minor and do not affect the safety and effectiveness.

Substantial Equivalence Discussion

The GuruNanda Dry Mouth Oral Rinse and GuruNanda Dry Mouth Oral Spray are substantially equivalent to Biotene Dry Mouth Oral Rinse and Biotene Moisturizing Mouth Spray (K123731) in intended use, design, materials, chemical composition, and performance.

Substantial Equivalence Comparison

The GuruNanda Dry Mouth Oral Rinse and GuruNanda Dry Mouth Oral Spray are substantially equivalent to Biotene Dry Mouth Oral Rinse and Biotene Moisturizing Mouth Spray (K123731) in intended use, design, materials, chemical composition, and performance.

An overview side-by-side comparison of the GuruNanda Dry Mouth Oral Rinse and GuruNanda Dry Mouth Oral Spray, and Biotene Dry Mouth Oral Rinse and Biotene Moisturizing Mouth Spray (K123731) as the predicate device is presented below.

Comparison of GuruNanda Dry Mouth Products with Biotene (K123731) Predicate Device

	Guru Nanda Dry Mouth Oral Rinse and Oral Spray	**Biotene Dry Mouth Oral Rinse and Biotene Moisturizing Mouth Spray (K123731)**
510(k) Number	K231205	K123731
Product Code	LFD	LFD
Device Common Name	Saliva, Artificial	Saliva, Artificial
Device Trade Name	GuruNanda Private Label Dry Mouth Oral Rinse and Oral Spray	Biotene Dry Mouth Oral Rinse and Biotene Moisturizing Mouth Spray
FDA Class	Unclassified	Unclassified
Regulation	Unclassified	Unclassified
Manufacturer	GuruNanda, LLC	GSK Consumer Healthcare
Product Family	Oral Rinse & Oral Spray	Oral Rinse & Oral Spray
Sold Sterile	No	No
Target Population	Unsupervised consumer use	Unsupervised consumer use
Anatomical Site	Mouth	Mouth
Method of Use	Ready to use liquid	Ready to use liquid
Disease State	Xerostomia	Xerostomia
Mode of Action	Contains ingredients that	Contains ingredients that

	temporarily substitute the feel of natural saliva to moisturize, lubricate and refresh the mouth, thereby diminishing dry mouth discomfort	temporarily substitute the feel of natural saliva to moisturize, lubricate and refresh the mouth, thereby diminishing dry mouth discomfort
Intended Use / Indications for Use	Relieve the symptoms of dry mouth: refresh, moisturize, clean, soothe oral irritation, and lubricate oral dryness	Relieve the symptoms of dry mouth: refresh, moisturize, clean, soothe oral irritation, and lubricate oral dryness
Labeling / Instructions for Use	Consumer use instructions on labels	Consumer use instructions on labels
Applications Per Day	As needed	As needed
Appearance	Clear, water-thin liquid	Clear, water-thin liquid
Color	Colorless	Colorless
Odor	Characteristic (Mint)	Characteristic (Mint)
Biocompatibility	Cytotoxicity, sensitization, irritation tested and passed in conformity with ISO 10993-5, ISO 10993-10, 10993-23	Cytotoxicity, sensitization, irritation tested and passed in conformity with ISO 10993-5, ISO 10993-10, 10993-23
Shelf-Life	2 years	3 years
Flavor	Mint Flavor	Mint Flavor
Description	The GuruNanda Dry Mouth Oral Rinse, GuruNanda Dry Mouth Oral Spray, are specifically formulated as an artificial saliva substitute with water, moisturizers, humectants, sweeteners, and flavors that collectively have lubricating,	Biotene Dry Mouth products are formulated as an artificial saliva substitute with water, moisturizers, humectants, sweeteners, and flavors that collectively have lubricating, moisturizing, soothing, and refreshing properties to help

	moisturizing, soothing, and refreshing properties to help relieve and manage the symptoms of dry mouth (xerostomia)	relieve and manage the symptoms of dry mouth (xerostomia)

Discussion of differences:

As shown in the side-by-side comparison of the GuruNanda Dry Mouth Oral Rinse and Oral Spray and the predicate device, Biotene Dry Mouth products (K123731), the artificial saliva products are virtually identical in formulation. The variations in the formula / composition do not affect the function, indications or equivalency of the proposed products, they are primarily related to ingredients used as preservatives.

In summary, these differences in formulation to the predicate devices do not alter the function, indications, or substantial equivalency of the products. Additionally, the variations in the formula / composition are designated as GRAS ingredients, food additives or have a significant history of use in dental and medical or food applications. All components of the product have been manufactured and tested using standardized and industry accepted state of the art production/test methods. The finished products have been tested using standardized and industry accepted test methods.

Based on the side-by-side comparison table above, it is apparent that GuruNanda Dry Mouth Oral Rinse and GuruNanda Dry Mouth Oral Spray, Biotene Dry Mouth Oral Rinse, Biotene Moisturizing Mouth Spray are not different in intended use and share the same fundamental technological characteristics. The minor design differences in the chemical compositions between the products and the product offerings (oral rinse, spray) does not raise different questions of safety and effectiveness than the predicate device. Based on the data presented, GuruNanda Dry Mouth Oral Rinse and GuruNanda Dry Mouth Oral Spray are artificial saliva that are substantially equivalent to Biotene Dry Mouth Oral Rinse and Biotene Moisturizing Mouth Spray.

Conclusion:

Based upon the similarity of the intended use and fundamental technology, together with the evaluation of physical and chemical characteristics, the GuruNanda Dry Mouth Oral Rinse and GuruNanda Oral Spray are substantially equivalent to Biotene Dry Mouth Oral Rinse and Biotene Moisturizing Mouth Spray(K123731) in intended use, design, materials, chemical composition, and performance.