Triumph Pharmaceuticals, Inc.
% H. Jenkins
Counsel
Wood Burditt Group
10 E. Scranton Ave., Ste. 201
Lake Bluff, Illinois 60044

February 15, 2019

Re: K181194
Trade/Device Name: SmartMouth DryMouth Oral Rinse
Regulatory Class: Unclassified
Product Code: LFD
Dated: January 17, 2019
Received: January 18, 2019

Dear H. Jenkins:

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

Digitally signed by Mary S. Runner -S3
Date: 2019.02.15 22:12:15 -05'00'

For Tina 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)*
K181194

Device Name
SmartMouth® DryMouth Oral Rinse

Indications for Use *(Describe)*

Provides relief of the symptoms and discomfort of dry mouth; refreshes, moisturizes, cleans, soothes oral irritation and lubricates oral dryness. Freshens breath.

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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K181194
510(k) Summary

Date prepared: February 15, 2019

Submitter / Contact Person	H. Carl Jenkins The Wood Burditt Group 10 E. Scranton Ave, Suite 201 Lake Bluff, IL 60044 (ph) 847-234-7500 x 205 (fax) 847-578-0728 (email) hcjenkins@woodburditt.com

Applicant	Triumph Pharmaceuticals, Inc. 12312 Olive Blvd., Ste. 250 St. Louis, MO 63141

Device

Trade Name	SmartMouth® DryMouth Oral Rinse
Proprietary Name	SmartMouth® DryMouth Oral Rinse
Common Name	Oral Rinse
Classification Name	Artificial Saliva
Classification Panel	Dental
Regulation	N/A (Unclassified Device)
Product Code	LFD
Classification	Unclassified

Device Description

SmartMouth® DryMouth Oral Rinse is a specially formulated water soluble artificial saliva with for use at home in the oral cavity. It is formulated with water, humectants/moisturizers, including two moisture-rich humectants that are plant based, thickeners/binders, buffers, sweeteners, flavor, and colorant that collectively have moisturizing, lubricating, soothing, and refreshing properties. The device is provided ready to use as a non-sterile, two-part semi-viscous green colored liquid packaged in white polyethylene terephthalate (PET) bottles with a clear polypropylene cap that present the liquid out of the polypropylene spout.

Indications for Use:

Provides relief of the symptoms and discomfort of dry mouth; refreshes, moisturizes, cleans, soothes oral irritation and lubricates oral dryness. Freshens breath.

Predicate Devices

Name	Biotene Dry Mouth Oral Rinse (Primary Predicate Device)
501(k) Number	K123731

Name	Hyrdris Oral Rinse (Reference Predicate Device)
501(k) Number	K163029

Technological characteristics and comparison

SmartMouth® DryMouth Oral Rinse is substantially equivalent to Biotene Dry Mouth Oral Rinse and Hyrdis Oral Rinse. They utilize the same fundamental scientific technology (a formulation of water, humectants or moisturizers, thickening/binding agents, buffering agents, sweeteners, flavor, surfactants and preservatives). All three devices also have substantially equivalent Indications for Use: predominantly providing relief from dry mouth.

Although the subject device and predicate devices are similar, the subject device differs slightly in terms of exact indications for use, packaging, labeling, and ingredient composition. In particular, the subject device indications for use includes a 'freshens breath' indication, but this addition (along with the corresponding differences in labeling) is an extension of the more general "refreshes" indication of the predicate devices. The ingredient composition of the subject device aligns with the composition of the product as it is marketed for cosmetic purposes, which is the reason for the two liquid system of the device. These differences however do not raise concerns of safety and effectiveness, as demonstrated by the physical properties comparison data generated from comparative testing of the subject device and the predicate devices, as well as the biocompatibility assessment conducted on the subject device. And despite these differences between the subject device and predicate devices, the predicate devices were selected as such by

the applicant because of the similarities in terms of overall indications for use, intended use, and mechanics of the dry mouth relief benefits provided by all three devices.

The following table provides a comparison between the proposed device and the predicate and reference devices:

Comparison of Predicate Devices to Proposed Device

	Primary Predicate Device	**Reference Device**	**Proposed device**
Trade Name	Biotene Dry Mouth Oral Rinse	Hydris Oral Rinse	SmartMouth® DryMouth Oral Rinse
510(k) Number	K123731	K163029	K181194
Classification Name	Artificial Saliva	Artificial Saliva	Artificial Saliva
Indications for Use	Relieves the symptoms of dry mouth,refresh, moisturize, clean, soothe oral irritation and lubricate oral dryness	Relieves the symptoms and discomfort of dry mouth, refresh, moisturize/hydrate, clean, soothe oral irritation and lubricate oral dryness.	Provides relief of the symptoms and discomfort of dry mouth; refreshes, moisturizes, rehydrates, cleans, soothes oral irritation and lubricates oral dryness. Freshens breath.
Dosage Form	Oral Rinse	Oral Rinse	Oral Rinse
Dosage (Per Use)	1 Tablespoon (~ 15 mL)	20 mL (4 teaspoons)	20 mL (4 teaspoons)
Method of Use	Ready to use liquid	Ready to use liquid	Ready to use liquid
Area of Use	Oral cavity	Oral cavity	Oral cavity
Applications/day	Up to 5 times daily	2 times daily	2 times daily
Prescription/OTC	OTC	OTC	OTC
Packaging	8 FL OZ, 16 FL OZ, 33.8 FL OZ bottles, designed for one-liquid formulation.	8 FL OZ, 16.9 FL OZ, 33.8 FL OZ bottles, designed for one-liquid formulation.	16 FL OZ, 32 FL OZ bottles, specially designed for two-liquid formulation of product as it is marketed for cosmetic purposes.

Other similarities between the subject device and predicate devices include the OTC intended home use; the same thickener/binder between the subject device and reference device; similar appearance, color, specific gravity, odor, pH, viscosity, and water content. Because of these similarities, the Biotene and Hydris products were selected by the applicant as the predicate devices, and any slight differences between the proposed device and the predicate devices do not raise issues of safety and effectiveness.

Non Clinical Tests performed:

Shelf-life stability testing, physical property comparison data, and a biocompatibility assessment demonstrate that the SmartMouth® DryMouth Oral Rinse (a) meets device specifications, and (b) is substantially equivalent to the predicate devices:

- Shelf-Life Stability Testing provides for a 36 month shelf life of the subject device, which is the same as the primary predicate device.
- Comparative physical property data of SmartMouth® DryMouth Oral Rinse and Predicate/Reference Devices demonstrate substantial equivalence in terms of Appearance, Color, Odor, pH, Viscosity, Specific Gravity, Water Content.
- Biocompatibility assessment accordance with the FDA guidance document "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and an analysis based on use of the product as an oral rinse, demonstrates that SmartMouth® DryMouth Oral Rinse is safe for use as directed.

Clinical test:
No clinical tests were conducted in support of this 510(k) submission.

Conclusion

Based upon similarities in indications for use and technology, as well as non-clinical performance testing, SmartMouth® DryMouth Oral Rinse is substantially equivalent to the predicate devices Biotene Dry Mouth Oral Rinse (K123731) and Hydris Oral Rinse (K163029).