DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Biopharm Consult, L.L.C.
David S. Johnson
President
5609 Hard Rock Place
Henrico, Virginia 23230

June 10, 2017

Re: K163029
Trade/Device Name: Hydris™ Oral Rinse
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: LFD
Dated: May 19, 2017
Received: May 22, 2017

Dear Mr. David Johnson:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mary S. Runner -A

Lori A. Wiggins, MPT, CLT
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)*
K163029

Device Name

Hydris™ Oral Rinse

Indications for Use *(Describe)*

"Relieves the symptoms and discomfort of dry mouth, refresh, moisturize/hydrate, 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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K163029

510(k) SUMMARY

Submission Date: June 19, 2017

510(k) Number: K163029

Submitter

Biopharm Consult, L.L.C.
5609 Hard Rock Place
Henrico, VA 23230

Contact: David S. Johnson
Phone: (973)-229-3731
Email: tampicoblue@yahoo.com

Proposed Device

Trade Name	Hydris™ Oral Rinse
Common Name	Oral Rinse
Classification Name	Saliva, Artificial
Regulatory Classification	Unclassified (pre-amendment)
Product Code	LFD
Review Panel	Dental Devices Panel

Primary Predicate Device

The predicate device for this submission is Biotene® Dry Mouth Oral Rinse (K123731), cleared on January 4, 2013. The primary predicate is one of three Biotene dry mouth products cleared in K123731 which contains both a gel and a spray formulation.

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

Reference Device

Trade Name	Medactive Oral Relief Spray/Gel
Common Name	Oral Rinse
Classification Name	Saliva, Artificial
Regulatory Classification	Unclassified (pre-amendment)
Product Code	LFD
Review Panel	Dental Devices Panel
501(k) Number	K152201
Submitter	GlaxoSmithKline Consumer Healthcare

Device Description

Hydris™Oral Rinse(Hydris) is a specially formulated water soluble artificial saliva substitute with a pH between 5.00 to 7.00 for use at home in the oral cavity. The proposed device 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/hydrating, lubricating, soothing, and refreshing properties. The device is provided ready to use as a non-sterile, semi-viscous blue colored liquid packaged in three sizes, including 8.5 FL OZ, 16.9 FL OZ and 33.8 FL OZ white polyethylene terephthalate (PET) bottles with white polypropylene caps. The shelf-life is 2 years.

Indications for Use

Relieves the symptoms and discomfort of dry mouth, refresh, moisturize/hydrate, clean, soothe oral irritation and lubricate oral dryness.

Comparison to Predicate Device

Hydris™Oral Rinse is substantially equivalent to Biotene® Dry Mouth Oral Rinse. The proposed device is not intended to be a drastic advance with new or medically significant benefits as compared to the predicate and thus does not lead to a new standard of care. The subject and predicate device have similar indication for use statements. They utilize the same fundamental scientific technology (a formulation of water, humectants or moisturizers, thickening/binding agents, buffering agents, sweeteners, flavor, surfactants and preservatives) and are similar in design, ingredients and packaging. The table 1 below provides a comparison between the proposed device and the predicate device.

Comparison of Predicate Device to Proposed device

	Predicate Device	Proposed device
Trade Name	Biotene® Dry Mouth Oral Rinse	Hydris™ Oral Rinse
510(k) Number	K123731	K163029
Classification Name	Artificial Saliva	Artificial Saliva
Product Code	LFD	LFD
Classification	Unclassified	Unclassified
Disease State	Xerostomia (Dry Mouth)	Xerostomia (Dry Mouth)
Intended Use	1. Provides symptom relief from Dry Mouth and low saliva including: • Oral discomfort • Mucosal soft tissue dryness • Oral side effects of illness, therapies, and medications 2. Soothes moistens and lubricates 3. Hydrates soft tissue"	To relieve the symptoms and discomfort of dry mouth, refresh, moisturize/hydrate, clean, soothe oral irritation and lubricate oral dryness.
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.
Dosage Form	Oral Rinse	Oral Rinse
Dosage (Per Use)	1 Tablespoon (~ 15 mL)	20 mL (4 teaspoons)
Method of Use	Ready to use liquid	Ready to use liquid
Area of Use	Oral cavity	Oral cavity
Applications/day	Up to 5 times daily	Up to 2 times daily
Prescription/OTC	OTC	OTC
Environment of Use	Home use	Home Use
Solvent	Water	Water
Humectants/Moisturizers	Glycerin, Propylene Glycol	Glycerin, Propylene Glycol
Sweeteners/Humectants	Xylitol, Sorbitol	Sorbitol, Sodium Saccharin, Sucralose
Thickeners/Binders	Hydroxyethyl Cellulose	Cellulose Gum, Xanthan Gum, Carbomer
Surfactant	Poloxamer 407	Poloxamer 407
Preservatives	Sodium Benzoate, Methylparaben, Propylparaben	Cetylpyridinium chloride, Sodium Benzoate
Flavor	Flavor	Flavor
Buffers	Disodium Phosphate, Sodium Phosphate	Disodium Phosphate, Sodium Phosphate
Colorant	None	FD&C Blue 1

Indications for Use Discussion

The wording found in the indications for use statement of the proposed Hydris™ Oral Rinse is consistent with that of the legally marketed primary predicate device, Biotene® Dry Mouth Oral Rinse. While there are differences in the wording of the indications-for-use statement for primary predicate Biotene Dry Mouth Oral Rinse and the proposed device Hydris Oral Rinse™ both devices share the same intended use, namely to provide symptomatic relief/treatment of dry mouth. Both the subject and predicate devices are also OTC.

Technological Characteristic Discussion

The predicate and proposed devices utilize the same fundamental technology. The mode of action of Hydris™Oral Rinse is substantially equivalent to that of the predicate device. The chemical composition of the proposed Hydris™Oral Rinse is similar to the primary predicate device Biotene® Dry Mouth Oral Rinse. Both the proposed and predicate devices contain ingredients such as water, humectants or moisturizers, thickening/binding agents, buffering agents, sweeteners, flavor, surfactants and preservatives, and both Hydris™Oral Rinse and its primary predicate Biotene® Dry Mouth Oral Rinse are similar in design, ingredients and packaging. Below is a summary of the technological characteristics compared to the primary predicate device.

Summary of Technological Characteristics Compared to Predicate Device

	Predicate Device	**Proposed Device**
Appearance	Semi-viscous liquid	Semi-viscous blue liquid
Specific Gravity	1.08	1.04-1.08
pH	6.4	5.0-7.0
Solubility	Water Soluble	Water Soluble
Packaging Unit	8 FL OZ, 16 FL OZ, 33.8 FL OZ bottles	8 FL OZ, 16.9 FL OZ, 33.8
Packaging Material - Bottle	White polyethylene terephthalate (PET)	White polyethylene terephthalate (PET)
Packaging Material - Cap	Polypropylene	Polypropylene
Prescription/OTC	OTC	OTC
Sterility	Non-Sterile	Non- Sterile
Shelf-Life	36 months	24 Months

Discussion of Differences

There are also several differences between the proposed device and its primary predicate.
In particular, the variations in formula/composition for Hydris™Oral Rinse from the primary predicate device are as follows:

- **Sweeteners**: Both devices use aqueous solutions and a sweetener, such as xylitol, sucralose or sodium saccharin as the sweetener. The proposed device features sodium Saccharin and sucralose as sweeteners, while the primary predicate employs xylitol. While the sweeteners vary between the two, in both predicate and proposed devices,
  the sweeteners are used to create a plant flavoring system and were chosen for their compatibility with the formula and the flavor.

- **Rheology Modifiers:** Cellulose gum (carboxymethylcellulose, or CMC) was chosen
  as a thickener/rheology modifier for the gel based on its significant history of use in dental, oral care and food products. Xanthan gum was chosen for the proposed device for similar reasons. The resulting viscosity in the proposed Hydris™Oral Rinse and its predicate Biotene® Dry Mouth Oral Rinse are similar in nature to the predicate device.

- **Preservatives:** An intentional decision was made not to use parabens in the proposed device. Alternatively, cetylpyridinium chloride, was added as a preservative as it is compatible with the formula at the given pH range. The choice of a binary preservative system results in an adequately preserved formulation of the proposed device when compared to its primary predicate. Despite differences in formula ingredients, these ingredients share similar functional roles within the formulas of both the proposed and predicate devices.

To address the ingredients included in the proposed device, but not found in the primary predicate, a reference device, MedActive Gel and Spray (K152201), was introduced as it is a dry mouth formulation which contains the ingredients not found in the primary predicate. The table below distinguishes the specific ingredients found in Biotene® Dry Mouth Oral Rinse from those identified in the reference device, MedActive Gel and Spray.

Identification of Ingredients in the Proposed Hydris™Oral Rinse and the Primary Predicate or Reference Device Source

Hydris™ Oral Rinse	**Primary Predicate or "Reference Predicate"**	**510(k) Number**
Water	Biotene® Dry Mouth Oral Rinse	K123731
Glycerin	Biotene® Dry Mouth Oral Rinse	K123731
Propylene Glycol	Biotene® Dry Mouth Oral Rinse	K123731
Sorbitol	Biotene® Dry Mouth Oral Rinse	K123731
Sodium Phosphate	Biotene® Dry Mouth Oral Rinse	K123731
Poloxamer 407 (ethylene Oxide Propylene Copolymer	Biotene® Dry Mouth Oral Rinse	K123731
Sodium Benzoate	Biotene® Dry Mouth Oral Rinse	K123731
Flavor	Biotene® Dry Mouth Oral Rinse	K123731
Disodium Phosphate	Biotene® Dry Mouth Oral Rinse	K123731
Cellulose Gum	Medactive Oral Relief Gel	K152201
Xanthan Gum	Medactive Oral Relief Spray	K152201
Cetylpyridinium Chloride	Biotene® Moisturizing Spray	K123731*
Carbomer (2-Propenoic Acid Homopolymer)	Biotene® New Oral Balance Gel	K123731*
Sodium Saccharin	Medactive Oral Relief Gel Spray	K152201
Sucralose	Medactive Oral Relief Gel and Spray	K152201

*****K12373 also contained a gel and a spray dry mouth formulation.

Ingredients: Water, Glycerin, Propylene Glycol, Sorbitol, Sodium Phosphate, Poloxamer 407 (ethylene Oxide Propylene Copolymer), Sodium Benzoate, Flavor, Disodium Phosphate, Cellulose Gum, Xanthan Gum, Cetylpyridinium Chloride, Carbomer (2-Propenoic Acid Homopolymer), Sodium Saccharin, and FD&C Blue 1.

All other variations in the formula/composition are concentration and volume variations of common ingredients to allow proper dispensing and use of the product and do not affect the function, indications, or equivalency of the proposed product. In summary, these differences in formulation to the predicate devices do not alter the function, indications, or substantial equivalency of the products.

In addition, the following is true:

- Any new components/ingredients are designated GRAS ingredients, food additives or have a significant history of use in dental & medical or food applications.

- All components of the product have been manufactured using standardized and industry accepted state of the art production methods.

- All components of the product have been tested using standardized and industry accepted state of the art test methods.

- The products have been tested using standardized and industry accepted state of the art test methods.

Discussion of Substantial Equivalence

The chemical components in Hydris™ Oral Rinse have been used in predicate devices, are listed as GRAS ingredients, are approved food additives/ingredients, or a combination these conditions. These facts well support the compatibility of Hydris™ Oral Rinse, and that the proposed device is substantially equivalent to the predicate devices, in terms of properties, intended use and composition.

Performance Data

The following nonclinical data have been provided in support of the substantial equivalence determination.

Nonclinical Testing

- Bench testing comparing Hydris™ Oral Rinse to Biotene® Dry Mouth Oral Rinse, the predicate device was performed. It was demonstrated that Hydris and Biotene are not significantly different in their ability to retain moisture/hydration, or in the moisturization/hydration of soft tissue at a specific time and temperature.

- Comparative studies of Hydris™Oral Rinse with Biotene® Dry Mouth Oral Rinse by Near Infrared Spectroscopy.

- Shelf-Life Stability Report (Hydris™ Oral Rinse)

- Post-Approval Stability Protocol and Stability Commitment

Bench Testing Results for Hydris™ Oral Rinse

Test	Result
Retention of Moisture	Pass / Not statistically different
Moisturization/Hydration of Soft tissue	Pass / Not statistically different

Sterilization/Shelf-Life

	Predicate Device	Hydris™ Oral Rinse
Packaging Unit	8 FL OZ, 16, FL OZ, 33.8 FL OZ bottles	8 FL OZ, 16.9 , FL OZ, 33.8 FL OZ bottles
Packaging Material - Bottle	White polyethylene terephthalate (PET)	White polyethylene terephthalate (PET)
Packaging Material - Cap	Polypropylene	Polypropylene
Sterility	Non-Sterile	Non- Sterile
Shelf-Life	36 Months	24 Months*

*24 months was chosen to harmonize shelf-life with Sponsor's marketed rinses in the United States.

Conclusion

Hydris™Oral Rinse(Hydris) has the same intended use and the same fundamental scientific technology as that of the legally marketed predicate device, Biotene® Dry Mouth Oral Rinse ®. This is demonstrated by comparing Hydris™ Oral Rinse's indications-for-use statement and technological characteristics and performance data (retention of moisture and moisturization/hydration of soft tissue) with those of primary predicate Biotene® Dry Mouth Oral Rinse. On this basis, Hydris™Oral Rinse is substantially equivalent to the legally marketed predicate device, Biotene® Dry Mouth Oral Rinse. Results from a biocompatibility assessment and performance testing further demonstrate substantial equivalence.

This 5l0(k) summary is submitted in accordance with the requirements of 21 CFR 807.