March 16, 2018

Dr. Harold Katz, LLC (dba TheraBreath)
% Barbara Fant
President
Clinical Research Consultants, Inc.
3308 Jefferson Avenue, Upper Level
Cincinnati, Ohio 45220

Re: K171542
Trade/Device Name: TheraBreath Dry Mouth Oral Rinse, TheraBreath Dry Mouth Lozenges
Regulatory Class: Unclassified
Product Code: LFD
Dated: February 7, 2018
Received: February 9, 2018

Dear Barbara Fant:

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.

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.

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,

Andrew I. Steen -S

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

4. Indications for Use Statement

510(k) Number (if known): To Be Assigned K171542

Device Name: TheraBreath Dry Mouth Oral Rinse

TheraBreath Dry Mouth Lozenges

Indications for Use:

TheraBreath Dry Mouth Oral Rinse is intended for relief of dry mouth symptoms and is indicated for use to refresh, moisturize, lubricate and soothe the oral cavity, and alleviate discomfort due to dry mouth.

TheraBreath Dry Mouth Lozenges are intended for relief of dry mouth symptoms, and are indicated for use to refresh, moisturize, lubricated, and soothe the oral cavity, and alleviate discomfort due to 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

5. 510(k) Summary

510(k) Submission, Traditional; as required by (21CFR§807.92(c))

510(k) Owner: Dr. Harold Katz, LLC (dba TheraBreath)
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Los Angeles, California 90038
Telephone: 323-762-8518
Facsimile: 323-993-8327
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Contact Person: Barbara S. Fant, Pharm.D.
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3308 Jefferson Avenue, Upper Level
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E-Mail: bsfant@crc-regulatory.com

Date: March 15, 2018

Trade Name: TheraBreath Dry Mouth Oral Rinse
TheraBreath Dry Mouth Lozenges

Common name: Dry mouth oral rinse
Dry mouth mouthwash
Dry mouth lozenges

Classification Name: Saliva, Artificial; Unclassified

Product Code: LFD

Identification of a Legally Marketed Predicate Device

TheraBreath Dry Mouth Oral Rinse and TheraBreath Dry Mouth Lozenges are substantially equivalent to the legally marketed predicate device: MedActive Oral Relief Spray and MedActive Oral Relief Gel, marketed by Medactive Oral Pharmaceuticals, LLC, Premarket Notification Number: K152201, FDA Product Code LFD (Saliva, Artificial; Unclassified); and

to the reference devices: Dr. Fresh Orazyme Dry Mouth Mouthwash marketed by Dr. Fresh, LLC, 510(k) Premarket Notification Number: K111250, FDA Product Code LFD (Saliva, Artificial; Unclassified); and, SST 100 Lozenges marketed by Hexim Pharmaceuticals, 510(k) Premarket Notification Number: K023046, FDA Product Code LFD (Saliva, Artificial; Unclassified).

General Description

TheraBreath Dry Mouth Oral Rinse and TheraBreath Dry Mouth Lozenges are specifically formulated as an artificial saliva substitute with moisturizers, humectants and salivary enzymes with lubricating, moisturizing and soothing properties to relieve the symptoms of dry mouth. In addition, TheraBreath Dry Mouth Lozenges continuously moisten the mouth to relieve the symptoms of Dry Mouth and to refresh breath. TheraBreath Dry Mouth Oral Rinse and TheraBreath Dry Mouth Lozenges are sugar-free, alcohol-free, and gluten-free.

TheraBreath Dry Mouth Oral Rinse is packaged in 16 ounce size bottles and is Tingling Mint flavored. TheraBreath Dry Mouth Lozenges are Mandarin Mint flavored and are sold in boxes of 24, 72, or 100 lozenges.

Intended Use/Indications for Use

TheraBreath Dry Mouth Oral Rinse is intended for relief of dry mouth symptoms and is indicated for use to refresh, moisturize, lubricate and soothe the oral cavity, and alleviate discomfort due to dry mouth.

TheraBreath Dry Mouth Lozenges are intended for relief of dry mouth symptoms, and are indicated for use to refresh, moisturize, lubricated, and soothe the oral cavity, and alleviate discomfort due to dry mouth.

TheraBreath Dry Mouth Program

When the TheraBreath dry mouth products are used together along with routine oral cleansing (i.e., toothbrushing), it provides a simple three-step solution to clean and moisturize the mouth:

- Step 1, Cleansing: Brush with TheraBreath Dry Mouth Toothpaste at least twice daily.
- Step 2, Rinsing: Rinse with TheraBreath Dry Mouth Oral Rinse after brushing, for up to 12 hours of dry mouth relief.
- Step 3, Moisturizing: Use TheraBreath Dry Mouth Lozenges for convenience and moisturizing during the day, as often as required, to effectively relieve oral dryness by temporarily lubricating and moisturizing the mouth.

Comparison of Technological Characteristics

TheraBreath Dry Mouth Oral Rinse and TheraBreath Dry Mouth Lozenges are substantially equivalent to Dr. Fresh Orazyme Dry Mouth Mouthwash (K111250) and to MedActive Oral Relief Spray and Gel (K152201) in intended use, design, materials, chemical composition, and performance. The products are all artificial saliva agents designed for relief from dry mouth symptoms. TheraBreath Dry Mouth Oral Rinse and Dr. Fresh Orazyme Dry Mouth Mouthwash both contain salivary enzymes. The TheraBreath and MedActive products contain Spilanthes Extract as a flavor. TheraBreath Dry Mouth Oral Rinse and TheraBreath Dry Mouth Lozenges are both manufactured for and distributed in the U.S.A. by Dr. Harold Katz, LLC (dba TheraBreath; Los Angeles, California). Dr. Fresh Orazyme Dry Mouth Mouthwash is manufactured and distributed in the U.S.A. by Dr. Fresh, LLC (Buena Park, California). MedActive Oral Relief Spray and Gel are manufactured and distributed in the U.S.A. by MedActive Oral Pharmaceuticals, LLC (Odessa, Florida).

The primary technological differences between the oral rinses are that: (1) the proprietary composition of the salivary enzymes in TheraBreath and Orazyme products are very similar, but not identical; (2) the product raw materials and chemical composition are similar, but not identical; and, (3) the TheraBreath products are directed for use as needed, whereas, Orazyme is directed for use 2 to 3 times per day.

Brief Summary of Non-Clinical Tests and Results

Testing of the TheraBreath dry mouth products was performed to determine product composition and demonstrate conformity with product specifications for color, appearance, pH, specific gravity, and preservative efficacy. Biocompatibility testing of the TheraBreath oral rinse and lozenge formulations was performed according to ISO 10993-5 for cytotoxicity and according to ISO 10993-10 for mucosal sensitization and irritation. The products passed all tests in conformity with the standards and testing determined that the TheraBreath dry mouth products were non-cytotoxic, non-sensitizing, and non-irritating. Accelerated aging testing was performed to establish a 3 year shelf-life for TheraBreath Dry Mouth Oral Rinse and real-time aging was performed to establish a 2 year shelf-life for TheraBreath Dry Mouth Lozenges.

Comparative laboratory testing was performed for TheraBreath Dry Mouth Oral Rinse and Dr. Fresh Orazyme Dry Mouth Mouthwash and confirmed that the physical properties were similar for the two products for pH, specific gravity, odor, color and appearance.

	TheraBreath Dry Mouth Oral Rinse	TheraBreath Dry Mouth Lozenges	Dr. Fresh Orazyme Dry Mouth Mouthwash (Reference Device)	MedActive Oral Relief Spray, Gel (Predicate)	Same or Different
Biocompatible	Yes	Yes	Yes	Yes	Same. TheraBreath products passed testing criteria in conformity with ISO 10993-5 and 10993-10 for cytotoxicity, irritation, and sensitization.
Physiologic Physico-Chemical Characteristics	Yes	Yes	Yes	Yes	Similar pH, specific gravity, color, odor and appearance for oral rinse formulations

Basis of Substantial Equivalence

TheraBreath Dry Mouth Oral Rinse and TheraBreath Dry Mouth Lozenges are substantially equivalent to Dr. Fresh Orazyme Dry Mouth Mouthwash (K111250) and to MedActive Oral Relief Spray and Gel (K152201) in intended use, design, materials, chemical composition, and performance as artificial saliva products designed for relief from dry mouth symptoms. The ingredients used to formulate TheraBreath Dry Mouth Oral Rinse and TheraBreath Dry Mouth Lozenges are used in the predicate and reference devices, which are legally marketed for the same intended use and indications. Technological characteristics of the TheraBreath products and predicate and reference devices are summarized in the table below and support the substantial equivalence of the products.

	TheraBreath Dry Mouth Oral Rinse	TheraBreath Dry Mouth Lozenges	Dr. Fresh Orazyme Dry Mouth Mouthwash (Reference Device)	MedActive Oral Relief Spray, Gel (Predicate)	Same or Different
Intended Use	Relief of dry mouth symptoms	Relief of dry mouth symptoms	Relief of dry mouth symptoms	Relief of dry mouth symptoms	Same
Indications for Use	TheraBreath Dry Mouth Oral Rinse is intended for relief of dry mouth symptoms and is indicated for use to refresh, moisturize, lubricate and soothe the oral cavity, and alleviate discomfort due to dry mouth.	TheraBreath Dry Mouth Lozenges are intended for relief of dry mouth symptoms, and are indicated for use to refresh, moisturize, lubricated, and soothe the oral cavity, and alleviate discomfort due to dry mouth.	Relieves the symptoms of dry mouth, while moisturizing and lubricating oral dryness.	Provides symptom relief from Dry Mouth and low saliva including: Oral discomfort, Mucosal soft tissue dryness, Oral side effects of illness, therapies, and medications. Soothes moistens and lubricates. Hydrates soft tissue.	Indications for artificial salivas differ slightly based on product offering
Disease State	Xerostomia	Xerostomia	Xerostomia	Xerostomia	Same
Area of Use	Oral cavity	Oral cavity	Oral cavity	Oral cavity	Same
Product Offering	Liquid oral rinse	Oral Lozenge	Liquid Oral Rinse	Spray, Gel	Different, unique to each Product A technological difference is the lozenge which is supported by the SST 100 Lozenges (K023046) reference device
Enzymes	Yes	No	Yes	No	Similar for products containing enzymes
Flavor/Moisturizer	Yes	Yes	Yes	Yes	Similar, formulation unique to each product
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Same
Xylitol	Yes	Yes	Yes	Yes	Same
Color Additive	No	No	No	No	Same
Sugar-Free/Gluten-Free	Yes	Yes	Yes	Yes	Same
Intended Population	Unsupervised consumer use	Unsupervised consumer use	Unsupervised consumer use	Unsupervised consumer use	Same

Applications Per Day	As needed	As needed	2-3 times/day	As needed	Similar, instructions for use are unique to each product offering

	TheraBreath Dry Mouth Oral Rinse	TheraBreath Dry Mouth Lozenges	Dr. Fresh Orazyme Dry Mouth Mouthwash (Reference Device)	MedActive Oral Relief Spray, Gel (Predicate)	Same or Different
Biocompatible	Yes	Yes	Yes	Yes	Same. TheraBreath products passed testing criteria in conformity with ISO 10993-5 and 10993-10 for cytotoxicity, irritation, and sensitization.
Physiologic Physico-Chemical Characteristics	Yes	Yes	Yes	Yes	Similar pH, specific gravity, color, odor and appearance for oral rinse formulations