K111250

APR 27 2012

510(K) Summary: Product Code LFD

1. Submitter Information

Name:	Dr. Fresh, Inc.
Address:	6645 Caballero Blvd. Buena Park, CA 90620
Contact Person:	Gary Pendyala
Telephone:	714.690.1573 Office 714.690.1572 FAX

2. Device Name

Device Name:	Dry Mouth Mouthwash
Trade or Proprietary Name:	Dr. Fresh Dry Mouth Mouthwash
Common or Usual Name:	Saliva, Artificial
Classification Name:	Saliva, Artificial

3. Identification of Equivalence

GlaxoSmithKline Consumer Healthcare	Biotene Dry Mouth Oral Rinse (K101477)

4. Device Description

Dr. Fresh Dry Mouth Mouthwash is a specifically formulated artificial saliva substitute which contains moisturizers, humectants and patent pending salivary enzymes that have lubricating, moisturizing and soothing properties to relieve the symptoms of Dry Mouth. The liquid product is supplied in 1.5 oz, 16 oz and 33.8 oz PET bottles.

5. Statement of Intended Use

Relieves the symptoms of dry mouth, cleans, soothes oral irritation, lubricates and moisturizes dry mouth irritation and diminishes dry discomfort.
Indications for Use: Relieves the symptoms of dry mouth, while moisturizing and lubricating oral dryness.

6. **Summary of Technological Characteristics**
Characteristics of the Device Compared to the Predicate Device

SUBSTANTIAL EQUIVALENCE COMPARISON CHART

Product	**Dr. Fresh Dry Mouth Mouthwash**	**Biotene Dry Mouth Oral Rinse**
Intended Use	Relieves the symptoms of dry mouth, cleans, soothes oral irritation, lubricates and moisturizes dry mouth irritation and diminishes dry discomfort.	Relieves and treats the symptoms of dry mouth; refreshes mouth odors, cleans soothes oral irritations, moisturizes, lubricates, and diminishes dry discomfort
Dosage	*As Needed* *One tablespoon for every use*	*As Needed* *One tablespoon for every use*
Disease State	*Xerostomia*	*Xerostomia*
Packaging	*1.5 oz, 16 oz and 33.8 oz PET bottles with flip caps*	*16 OZ brick shaped white PETE bottle with flip cap*
Functional Ingredients	*See Ingredient Comparison chart in Substantial Equivalence Discussion*	*See Ingredient Comparison chart in Substantial Equivalence Discussion*
Area of Use	*Oral Cavity*	*Oral Cavity*
Type of Product	*Liquid Solution*	*Liquid Solution*
Presentation	*Non-Sterile*	*Non-Sterile*

7. **Biocompatibility .**
Dr. Fresh Dry Mouth Mouthwash has been tested in accordance with ISO 10993 and was shown to meet the requirements of biocompatibility testing in the categories of irritation, cytotoxicity and contact sensitization.

8. **Discussion and Conclusion**
Based on the comparison of intended use and technical characteristics, we conclude that Dr. Fresh Dry Mouth Mouthwash is substantially equivalent to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 27 2012

Dr. Fresh, Inc.
C/O Ms. Camille Thornton
Senior Regulatory Specialist
Registrar Corp
144 Research Drive
Hampton, Virginia 23666

Re: K111250
Trade/Device Name: Dry Mouth Mouthwash
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LFD
Dated: October 25, 2011
Received: March 28, 2012

Dear Ms. Thornton:

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.

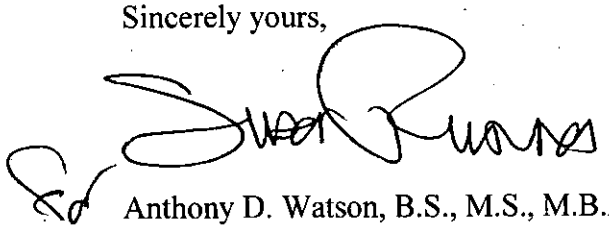
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111250

Indications for Use

510(k) Number (if known): N/A

Device Name: Dry Mouth Mouthwash

Indications For Use:

Relieves the symptoms of dry mouth, while moisturizing and lubricating oral dryness.

Prescription Use: _____ AND/OR Over-The-Counter Use: X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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