DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 19, 2015

Elevate Oral Care
Mr. Steve Pardue
Managing Member
346 Pike Road, Suite 5
West Palm Beach, Florida 33411

Re: K150074
Trade/Device Name: Elevate Moisturizing Spray
Regulation Number: Unclassified
Regulation Name: Artificial Saliva
Regulatory Class: Unclassified
Product Code: LFD
Dated: March 19, 2015
Received: March 20, 2015

Dear Mr. Pardue:

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" (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 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 yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Division 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

Indications for Use

510(k) Number (if known): _____

Device Name: Elevate Moisturizing Spray

Indications for Use:

- Elevate Moisturizing Spray is indicated to provide comfort for individuals suffering from dry mouth. It is recommended to be used by people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth.
- Elevate Moisturizing Spray is indicated for rapid relief of dry mouth symptoms, to provide a protective coating inside the mouth and to help control bad breath.
- A mouth spray that quickly reduces mouth discomfort, oral malodor and other symptoms of dry mouth.

Prescription Use ___ ___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X_____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

346 Pike Road, Suite 5 • West Palm Beach, FL 33411
Phone: 877-866-9113 • Fax: 561-244-1927
www.elevateoralcare.com

5. 510(k) Summary

Submitter:

Company:	Elevate Oral Care
Street:	346 Pike Road, Suite 5
City, State Zip:	West Palm Beach, FL 33411
Country:	USA
Estab. Registration #:	3009603151
Correspondent:	Steve Pardue Managing Member
Phone:	877-866-9113
Fax:	561-244-1927
Email:	spardue@elevateoralcare.com
Date:	June 19, 2015

Name of Device

Proprietary Name:	Elevate Moisturizing Spray
Classification Name:	Saliva, Artificial Unclassified, pre-amendment
Common Name:	Saliva, Artificial
Product Code:	LFD

Predicate Devices

Primary Predicate Device	**510(k)**
Biotene Moisturizing Mouth Spray	K123731
Reference Device	**510(k)**
GC Moisturizing Gel	K101346

Description

Elevate Moisturizing Spray is a viscous liquid dispensed from a spray bottle into the mouth. The spray will coat the inside of the mouth for a period of time and create relief from dry mouth symptoms in those who suffer oral malodor, discomfort, difficulties eating or speaking from dry mouth complications.

Elevate Moisturizing Spray is equivalent to the primary predicate device Boitene Moisturizing Mouth Spray, and GC Moisturizing Gel in its intended use. All three products are artificial saliva agents designed for relief from dry mouth symptoms.

Indications for Use Comparison

Primary Predicate Device - Biotene Moisturizing Mouth Spray

- The Biotene Oral Balance Gel, Biotene Dry Mouth Oral Rinse and Biotene Moisturizing Mouth Spray intended use is to relieve the symptoms of dry mouth, refresh, moisturize, clean, soothe oral irritation and lubricate oral dryness.

Reference Predicate Device - GC Moisturizing Gel

- **GC** Oral Moisturizing Gel is designed to provide comfort for individuals suffering from dry mouth. It is recommended to be used for people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth.
- **GC** Oral Moisturizing Gel is indicated for the relief of dry mouth symptoms, to provide a protective coating inside the mouth, and help to control bad breath.

Elevate Moisturizing Spray

- Elevate Moisturizing Spray is designed to provide comfort for individuals suffering from dry mouth. It is recommended to be used by people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth.
- Elevate Moisturizing Spray is indicated for rapid relief of dry mouth symptoms, to provide a protective coating inside the mouth and to help control bad breath.
- A mouth spray that quickly reduces mouth discomfort, oral malodor and other symptoms of dry mouth.

All claims of all three devices are similar in nature and are for the relief of dry mouth symptoms and/or oral malodor.

Technological Characteristics

The chemical composition of Elevate Moisturizing Spray is similar to the predicate devices. These products contain ingredients such as water, sodium carboxymethylcellulose, flavorings, sweeteners, glycerol and various thickening agents. The combination of these ingredients provides a pleasant flavor, lubrication and increased retention in the mouth when used.

The mode of action of Elevate Moisturizing Spray is substantially equivalent to the predicate devices.

Summary of Physical Tests

Desorption Testing:

0.4g of each product was placed on a weighing dish and weighed followed by incubation at 37 degrees Celsius for 2 hours. A value obtained by dividing the weight change by the initial weight in terms of percentage was designated as moisture desorption degree.

Mean Percent Loss

Product	Percent Loss (%)
Elevate Moisturizing Spray (21914-1)	21.96
Biotene Mouth Spray	36.8
GC Mint Moisturizing Gel	17.15

Discussion of Differences

The variations in formula/composition for Elevate Moisturizing Spray from the predicate devices are as follows:

- **Solvent:** The main solvent in the current device and predicate devices is water. Other predicate devices used PEG-60 or Polyglycerol as additional solvents. Additional solvents were not needed to prepare Elevate Moisturizing Spray.
- **Mucoadhesive Agents:** A proprietary blend of ingredients were chosen as the mucoadhesive agent over Polyvinyl Alcohol (VP/VA) or carboxymethylcelulose (CMC). These base ingredients work together to create a semi-viscous fluid (similar to the predicate devices) that can be retained in the mouth for a period of time. While present, these ingredients will act as a lubricant and carry a humectant, maintaining a moist mouth feel for the patient.
- **Rheology Modifiers**: The same blend of ingredients that act as mucoadhesive agents, also increase the viscosity of the Elevate Moisturizing Spray to that of a semi-viscous liquid. This viscosity is similar in nature to the predicate devices.
- **Flavoring, Aromas, Sweeteners**: The flavorings in Elevate Moisturizing spray are similar in nature to the predicate devices although the specific flavor may differ based on stated label flavor. All devices use aqueous solutions and a sweetener such as xylitol as the sweetener.
- **Preservatives**: Xylitol, sugar and other sugar substitutes have been shown to act as preservatives in high concentrations (Int J Cosmet Sci. 2011 Oct;33(5):391-7). Xylitol was used to prevent microbial growth in the product.
- 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 performance of the product.
- These differences in formulation to the predicate devices do not alter the function, indications or performance of the product.

Description of Substantial Equivalence

The chemical components in Elevate Moisturizing Spray have been used in predicate devices, are listed as GRAS ingredients, are approved food additives/ingredients, or a combination these conditions. We believe these facts well support the compatibility of Elevate Moisturizing Spray, and that the applicant device is substantially equivalent to the predicate devices properties, intended use and composition.

Information provided in this submission confirms the substantial equivalence to the predicate devices with common indications. The data provided in this 510(k) submission also shows that the composition is safe for its intended use based on the biocompatibility assessment and risk assessment conduced according to ISO 10993 and ISO 14971.

This 5l0(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.