



February 27, 2026

Elevate Oral Care
Steve Pardue
Managing Member
346 Pike Rd.
Suite 5
West Palm Beach, Florida 33408

Re: K253778

Trade/Device Name: Allday Moisturizing Rinse
Regulatory Class: Unclassified
Product Code: LFD
Dated: November 26, 2025
Received: November 26, 2025

Dear Steve 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

The logo for the U.S. Food and Drug Administration (FDA) is displayed in a light blue color. It consists of the letters 'FDA' in a bold, sans-serif font. The 'F' and 'D' are connected at the top, and the 'A' is slightly larger and positioned to the right of the 'D'.

Bobak
Shirmohammadi -S

For Michael E. Adjodha, M.ChE., RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K253778

Device Name
Allday Moisturizing Rinse

Indications for Use (Describe)

Allday Moisturizing Rinse is indicated to provide relief from dry mouth, clean, refresh, and soothe oral tissues. It is recommended to be used by people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth.

Allday Moisturizing Rinse 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 rinse that quickly reduces mouth discomfort, oral malodor and other symptoms of 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K253778 - 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: November 12, 2015

Name of Device

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

Predicate Device

Primary Predicate Device	510(k)
Elevate Moisturizing Spray	K150074
Reference Device	510(k)
Biotene Dry Mouth Rinse	K123731

Description

Allday® Moisturizing Rinse is an oral moisturizing rinse that patients will use to alleviate dry mouth symptoms. They will swish or rinse with the product for 30 seconds and spit/expectorate into the sink. The rinse will coat the inside of the mouth for a period of time and relieve symptoms of dry mouth such as oral malodor, discomfort, difficulties eating or speaking.

Allday Moisturizing Rinse is equivalent to the primary predicate device Elevate Moisturizing Spray. Both products are artificial saliva agents designed for relief from dry mouth symptoms. The reference device is included to compare the subject device to a similar rinse delivery product.

Indications for Use Comparison

Allday Moisturizing Rinse

- Allday Moisturizing Rinse is indicated to provide relief from dry mouth, clean, refresh, and soothe oral tissues. It is recommended to be used by people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth.
- Allday Moisturizing Rinse 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 rinse that quickly reduces mouth discomfort, oral malodor and other symptoms of dry mouth.

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.

Biotene Dry Mouth Spray

- To relieve symptoms of dry mouth, refresh, moisturize, clean, soothe oral irritation and lubricate oral dryness.

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 Allday Moisturizing Rinse is nearly identical to the predicate device. These products contain ingredients such as water, 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 Allday Moisturizing Rinse is substantially equivalent to the predicate device.

Summary of Physical Tests

Allday Moisturizing Rinse conducted the same study Desorption test that Elevate Moisturizing Spray (Allday Dry Mouth Spray in the market) conducted. This is the most common test used by many products in LFD product code.

This comparison was completed using the reference device and the subject device as they are both rinse based products.

The results are summarized below.

Summary:

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.

	<i>Original Weight (g) - Exp 1, 2, 3, 4, 5</i>	<i>Moisture Loss (g) - Exp 1, 2, 3, 4, 5</i>	<i>% Moisture Desorbed (%)-1, 2, 3, 4, 5</i>	<i>Average % Moisture Desorbed</i>
All Day Dry Mouth Rinse P.1014, R&D#05705001	0.4043, 0.4022, 0.4037, 0.4062, 0.4068	0.1686, 0.1635, 0.1504, 0.1664, 0.1683	41.7%, 40.65%, 37.26%, 40.97%, 41.37%	40.39%
GSK Biotene Dry Mouth Rinse 3C036C Exp 2026-02-25	0.4061, 0.4028, 0.4001, .4043, 0.4086	0.2257, 0.2589, 0.1960, 0.2045, 0.2192	55.58%, 64.28%, 48.99%, 50.58%, 53.65%	54.61%

8				
9	Product	% Desorbed		
10	Allday Moisturizing Rinse	41.52	42.45	40.46
11	Allday Spray	27.06	30.39	29.33
12				
13	Chi Test P value	0.000232131		
14				

Discussion of Differences

The differences between the products is minimal and pertain to the mouth feel, taste and delivery of the products. The Subject device has added glycolipids for improved mouth feel, and sucralose to improve the flavor of the product as a rinse.

The remaining ingredients are identical in both the subject device and the predicate device. The formulas only contain different percentages of the ingredients to accommodate the different delivery methods; rinse in the subject device, spray in the predicate device.

Description of Substantial Equivalence

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

Information provided in this submission confirms the substantial equivalence to the predicate device 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 conducted according to ISO 10993 and ISO 14971.

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.