April 5, 2021

The Procter & Gamble Company
Brenda Fuentes
Regulatory Affairs Scientist
1 Procter & Gamble Plaza
Cincinnati, Ohio 45202

Re: K203567
Trade/Device Name: Oral-B Dry Mouth Oral Rinse
Regulatory Class: Unclassified
Product Code: LFD
Dated: January 4, 2021
Received: January 5, 2021

Dear Brenda Fuentes:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Michael E. Adjodha -S

Michael E. Adjodha, M.Ch.E.
Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K203567

Device Name

Oral-B® Dry Mouth Oral Rinse

Indications for Use *(Describe)*

Relieves the symptoms and discomfort of dry mouth, refreshes, moisturizes/hydrates, soothes oral irritation and lubricates oral dryness.

Provides long lasting relief for up to 6 hours.

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.***

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Procter&Gamble

*The Procter & Gamble Company*
*Mason Business Center*
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# 510(k) Summary

## SUBMITTER

**510(k) Owner:** The Procter & Gamble Company
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Cincinnati, Ohio 45202
Telephone: (513) 206-4331
**Owner/Operator Registration Number:** 9915005

**Contact Person:** Brenda S. Fuentes, B.S.
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Telephone: (513) 622-1384
E-Mail: fuentes.bs@pg.com

**Date Prepared:** December 3, 2020

## DEVICE

**Trade Name:** Oral-B® Dry Mouth Oral Rinse

**Common Name:** Artificial Saliva

**Classification Name:** Saliva, Artificial

**Product Code:** LFD

**Regulation Number:** Unclassified

**Device Classification:** Unclassified

**GMP exempt**: No

**Review Panel:** Dental

## PREDICATE / REFFERENCE DEVICE

Oral-B® Dry Mouth Oral Rinse (K201277)

The predicate device has not been the subject of any design-related recalls.

## DEVICE DESCRIPTION

The Oral-B® Dry Mouth Oral Rinse is a non-sterile clear liquid formulated as an artificial saliva (LFD) intended to be marketed over the counter for at-home use. The artificial saliva for dry mouth is formulated with gel film forming polysaccharides, sodium hyaluronate, which possess lubricating and moisturizing properties. Oral-B® Dry Mouth Oral Rinse also contains water, moisturizers/humectants, thickener, surfactant, pH adjusters, preservative, sweetener and flavor that collectively form the device formulated at a pH of 6 and designed to help relieve and manage the symptoms of dry mouth. A list of device components can be found in Table 5-1. None of the constituents used in the device are novel materials (i.e., materials not previously used in a legally marketed US-medical device).

The device is intended to be used for 30 seconds each use, up to five times daily for consumers 12 years or older. Oral-B® Dry Mouth Oral Rinse is supplied in a 16-fluid ounce white Polyethylene Terephthalate (PET) bottle, with a white polypropylene closure and a clear polypropylene dosing cup.

## INDICATIONS FOR USE

Relieves the symptoms and discomfort of dry mouth, refreshes, moisturizes/hydrates, soothes oral irritation and lubricates oral dryness.

Provides long lasting relief for up to 6 hours.

## COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Oral-B® Dry Mouth Oral Rinse (K201277) was granted a finding of substantial equivalence to GUM® HYDRAL™ Dry Mouth Oral Rinse (K181134) in its intended use, indication for use, design, chemical composition, packaging, shelf life and performance as artificial saliva product designed for relief from dry mouth symptoms during the 510(k) review process for K201277.

There are no formulation/technological changes to the Oral-B® Dry Mouth Oral Rinse subject device vs. the legally marketed Oral-B® Dry Mouth Oral Rinse predicate device K201277. The only change from K201277 Oral-B® Dry Mouth Oral Rinse cleared to market in September 2020 is the indication for use. The proposed indication for use change is from “4 HOURS” to “6 HOURS” in line with new clinical data supporting the efficacy duration.

There are no novel materials (i.e., materials not previously used in a legally marketed US-medical device) used in the manufacture of this device. The composition of the subject device is the same as that of the predicate device, with no differences in physical properties, biocompatibility or shelf life. The device directions for use have not changed.

The difference in indication for use does not raise any concerns of safety and effectiveness. The technological characteristics of the Oral-B® Dry Mouth Oral Rinse subject and predicate devices are summarized in the table below and support the substantial equivalence of the products.

**Table 5-1** Summary of Technological Characteristics

| Feature | Subject (K203567) | Predicate (K201277) |
|---|---|---|
| **Proprietary Name** | Oral-B® Dry Mouth Oral Rinse | Oral-B® Dry Mouth Oral Rinse |
| **Intended Use** | Relief of dry mouth symptoms | Relief of dry mouth symptoms |
| **Indication for Use** | Oral-B® Dry Mouth Oral Rinse: Relieves the symptoms and discomfort of dry mouth, refreshes, moisturizes/ hydrates, soothes oral irritation and lubricates oral dryness.<br>Provides long lasting relief for up to **6 hours**. | Oral-B® Dry Mouth Oral Rinse: Relieves the symptoms and discomfort of dry mouth, refreshes, moisturizes/ hydrates, soothes oral irritation and lubricates oral dryness.<br>Provides long lasting relief for up to **4 hours.** |
| **Target Population** | Xerostomic, dry mouth sufferer | Xerostomic, dry mouth sufferer |
| **Area of Use** | Oral Cavity/Mouth | Oral Cavity/Mouth |
| **Dose Form** | Oral Rinse | Oral Rinse |
| **Dosage** | 15 mL for 30 seconds up to 5 times a day | 15 mL for 30 seconds up to 5 times a day |
| **Prescription/OTC** | Over the Counter | Over the Counter |
| **Device Components** | Sodium Hyaluronate, Water, Xylitol, Sodium Benzoate, Benzoic Acid, Glycerin, Propylene Glycol, Poloxamer 407, Cetylpyridinium Chloride Carboxymethyl Cellulose, Flavor | Sodium Hyaluronate, Water, Xylitol, Sodium Benzoate, Benzoic Acid, Glycerin, Propylene Glycol, Poloxamer 407, Cetylpyridinium Chloride Carboxymethyl Cellulose, Flavor |
| **Packaging** | 16.9 fluid ounce Polyethylene Terephthalate (PET) bottle with white polypropylene cap. | 16.9 fluid ounce Polyethylene Terephthalate (PET) bottle with white polypropylene cap. |
| **Appearance** | Colorless, clear, transparent liquid | Colorless, clear, transparent liquid |
| **Odor** | Slight mint odor | Slight mint odor |
| **pH** | 5.5 – 6.4 | 5.5 – 6.4 |
| **Viscosity** | > 29 cP | > 29 cP |
| **Specific Gravity** | 1.04 | 1.04 |
| **Biocompatibility** | Risk assessment consistent with ISO 10993-1. | Risk assessment consistent with ISO 10993-1. |

## PERFORMANCE DATA

There are no formulation/technological changes to the Oral-B® Dry Mouth Oral Rinse subject device vs. the legally marketed Oral-B® Dry Mouth Oral Rinse predicate device K201277. The change in indication for use is supported by the clinical trial performance data summarized below.

### Clinical Testing

A controlled, randomized, 3-treatment, parallel clinical study was conducted to evaluate if Oral-B® Dry Mouth Oral Rinse and a marketed dry mouth rinse were more effective in relieving dry mouth symptoms, immediately and six hours after use, compared to water on day 1 and after eight days of product use. The results of this study demonstrated that Oral-B® Dry Mouth Oral Rinse was more effective than water at providing immediate dry mouth moisturization and overnight and up to 6 hours of relief of dry mouth symptoms. Analysis of the clinical study results support the Indication for Use statement of "Provides long lasting relief for up to 6 hours".

This clinical study included subjects with self-reported dry mouth symptoms as determined by an Oral Examination and subject responses to the Dry Mouth Inventory (DMI) questionnaire. While not all subjects experienced the same efficacy due to normal variation, the majority of study subjects using the subject device achieved dry mouth symptom relief at all time points including 4- and 6- hours post-treatment. The stated Indication For Use includes the phrase "for up to" as "Provides long lasting relief for up to 6 hours" in order to address the potential variability of benefit obtainable by consumers.

## CONCLUSION

Based on the intended use, technological characteristics, and the clinical data provided, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device (K201277).