



February 23, 2021

The Procter & Gamble Company
Michael Kaminski
Principal Scientist
8700 Mason Montgomery Road
Mason, Ohio 45040

Re: K201277
Trade/Device Name: Oral-B Dry Mouth Oral Rinse
Regulatory Class: Unclassified
Product Code: LFD

Dear Michael Kaminski:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 2, 2020. Specifically, FDA is updating this SE Letter to correct a misspelling of the company name as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Michael Adjodha, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, 301-796-6276, michael.adjodha@fda.hhs.gov.

Sincerely,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
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



September 2, 2020

The Proctor & Gamble Company
Michael Kaminski
Principal Scientist
8700 Mason Montgomery Road
Mason, Ohio 45040

Re: K201277

Trade/Device Name: Oral-B Dry Mouth Oral Rinse
Regulatory Class: Unclassified
Product Code: LFD
Dated: May 12, 2020
Received: May 13, 2020

Dear Michael Kaminski:

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

for Srinivas "Nandu" Nandkumar, Ph.D.

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

Indications for Use

510(k) Number (if known)

K201277

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 4 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.

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Procter & Gamble

The Procter & Gamble Company
Mason Business Center
Mason, Ohio 45040-9462

K201277 - 510(k) Summary

SUBMITTER

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

Contact Person: Michael A. Kaminski Ph.D.
Regulatory Affairs Principal Scientist
Oral Care
The Procter & Gamble Company
Telephone: (513) 206-4331
Email: kaminski.ma@pg.com

Date Prepared: September 1, 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 / REFERENCE DEVICE

GUM® HYDRAL™ Dry Mouth Oral Rinse (K181134)

To the best of our knowledge 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 4 hours.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Oral-B® Dry Mouth Oral Rinse is substantially equivalent to the predicate device 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. 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 that haven't been used in the predicate and/or reference devices. While the composition of the subject device is not the same as that of the predicate device, the differences do not raise any concerns of safety and effectiveness, as demonstrated by the similarities in physical properties, biocompatibility, shelf life and effectiveness. The technological characteristics of the Oral-B® Dry Mouth Oral Rinse 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	Predicate (K181134)
Proprietary Name	Oral-B® Dry Mouth Oral Rinse	GUM® HYDRAL™ 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. Provides long lasting relief for up to 4 hours.	GUM® HYDRAL™ Dry Mouth Oral Rinse helps soothe oral tissue and relieve the symptoms of dry mouth, refresh, moisturize, clean, soothe oral irritation and lubricate oral dryness.
Target Population	Xerostomic, dry mouth sufferer	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	Water, Sorbitol, Sodium Citrate, Polyvinylpyrrolidone, Propanediol, Betaine, Xylitol, PEG-40 Hydrogenated Castor Oil, Taurine, Citric Acid, Sodium Hydroxide, Methyl Paraben, Flavor, Sodium Hyaluronate, Cetylpyridinium Chloride, Sucralose, Stevia Extract
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	5.5-7.0
Viscosity	> 29 cP	20.39 Sct (22.0 cP*)
Specific Gravity	1.04	1.06
Biocompatibility	Risk assessment consistent with ISO 10993-1.	Biocompatibility testing in conformance with ISO 10993-1.

*Viscosity as measured by P&G

PERFORMANCE DATA

Biocompatibility Testing

Biocompatibility was demonstrated consistent with FDA guidance “*Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*”.

Non-Clinical Bench Testing

Comparative chemical and physical property data for the subject and predicate device support a finding of substantial equivalence in terms of pH, specific gravity, surface tension and viscosity.

Shelf life stability testing provides for a 24-month shelf life of the subject device.

Clinical Testing

A controlled, randomized, 3-treatment, 3-period crossover 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 four hours after use, compared to water on day 1 and after four 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 long-term relief of dry mouth symptoms. Analysis of the pilot study results support the Indications for Use statement of duration of effectiveness for up to 4 hours. Additionally, the data suggest that Oral-B[®] Dry Mouth Oral Rinse may be more effective than the comparator dry mouth oral rinse device.

CONCLUSION

Based on the intended use, technological characteristics, non-clinical performance data and the clinical data provided the subject device is as safe, as effective, and performs as well as the legally marketed predicate device (K181134).