November 5, 2019

SunBio, Inc.
% Stuart Goldman
Sr. Consultant, RA/QA
Emergo by UL
2500 Bee Cave Road; Bldg. 1, Suite 300
Austin, Texas 78746

Re: K190144
Trade/Device Name: MucoPEG
Regulatory Class: Unclassified
Product Code: LFD
Dated: August 9, 2019
Received: August 13, 2019

Dear Stuart Goldman:

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,

for Srinivas Nandkumar, Ph.D.
Acting 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)*
K190144

Device Name
MucoPEG™

Indications for Use *(Describe)*
MucoPEG™ is indicated to relieve the symptoms and discomfort of dry mouth, refresh, moisturize/hydrate, clean, soothe oral irritation, and lubricate oral dryness.

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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# K190144

# 510(k) Summary

# MucoPEG™

## 1. Submission Sponsor

SunBio, Inc.
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Contact: Ms. Sun S. Kim
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Phone: (925) 876-0439 (USA); 82-31-423-5467 (S. Korea)

## 2. Submission Correspondent

Emergo Global Consulting, LLC
2500 Bee Cave Road
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Austin, TX 78746

Contact: Stuart R. Goldman
Title: Senior Consultant RA/QA
Phone: (512) 327-9997

## 3. Date Prepared

March 13, 2019

## 4. Device Identification

Trade Name: MucoPEG™
Common Name: Artificial Saliva
Classification Name: Pre-Amendment
Regulation Number: Pre-Amendment
Product Code: LFD
Class: Unclassified
Classification Panel: Dental

## 5. Legally Marketed Predicate Device

Predicate Device – Hydris™ Oral Rinse (K163029; Product Code LFD)

## 6. Indications for Use Statement

MucoPEG™ is indicated to relieve the symptoms and discomfort of dry mouth, refresh, moisturize/hydrate, clean, soothe oral irritation, and lubricate oral dryness.

## 7. Device Overview

MucoPEG™ is an artificial saliva to relieve xerostomia symptoms and discomfort. The main ingredient of MucoPEG™ is a polyethylene glycol (PEG) derivative. The additives to MucoPEG™ are mint (for flavor) and sodium bicarbonate (for pH maintenance when dissolved in water). MucoPEG™ is formulated as a powder and packaged in a single-use packet.

## 8. Substantial Equivalence Discussion

The substantial equivalence comparison of MucoPEG™ to Hydris™ with respect to its intended use and technological characteristics (ingredients, conditions of use, physical properties and biocompatibility) is shown in **Table 5-1** and provides detailed information regarding the basis for the determination of substantial equivalence between the subject and predicate devices. Two additional reference devices, Neutrasal® (K093642) and Coseal® (P030039), are being added to this 510(k) for MucoPEG™ to incorporate technological features of the subject device that are not contained in the predicate device Hydris™.

**Table 5-1 – Substantial Equivalence Comparison**

| Attributes | Predicate Device | Subject Device | Similarities / Differences |
|---|---|---|---|
| **Regulatory Information** | | | |
| **Device Name** | Hydris™ Oral Rinse | MucoPEG™ | - |
| **Manufacturer** | Colgate-Palmolive | SunBio | - |
| **510(k) #** | K163029 | K190144 | - |
| **Product Code** | LFD | LFD | Same |
| **Regulation** | Pre-Amendment | Pre-Amendment | Same |
| **Class** | Unclassified | Unclassified | Same |
| **Review Panel** | Dental | Dental | Same |
| **Intended Use** | Temporary relief of xerostomia (i.e., dry mouth). | Temporary relief of xerostomia (i.e., dry mouth). | Same |
| **Indications for Use** | To relieve the symptoms and discomfort of dry mouth, refresh, moisturize/hydrate, clean, soothe oral irritation, and lubricate oral dryness. | To relieve the symptoms and discomfort of dry mouth, refresh, moisturize/hydrate, clean, soothe oral irritation, and lubricate oral dryness. | Same |
| **Ingredients** | | | |
| **Solvent** | $H_2O$ | $H_2O$ | Same |
| **Humectants/Moisturizers** | Glycerin, Propylene Glycol (PG) | Polyethylene Glycol (PEG) Tetra Succinimidyl Glutarate | Similar. The PEG used in the subject device and the PG used in the predicate device provide the same mechanical mechanism of action and are alkylene oxide by-products sourced from the petroleum refining process, and then purified to USP grade. |

| | | | |
|---|---|---|---|
| **Buffers** | Disodium Phosphate, Sodium Phosphate | Sodium Bicarbonate | Similar. These different buffering agents are generally recognized as safe (GRAS) and provide similar pH levels for the subject and predicate devices. |
| **Flavors** | Mint | Mint | Same |
| **Thickeners** | Cellulose Gum, Xanthan Gum, Carbomer | None | Thickeners are not used in the subject device. |
| **Surfactants** | Poloxamer 407 | None | Surfactants are not used in the subject device. |
| **Preservatives** | Cetylpyridinium Chloride, Sodium Benzoate | None | Preservatives are not used in the subject device. |
| **Colorants** | FD&C Blue 1 | None | Colorants are not used in the subject device. |
| **Sweeteners** | Sorbitol, Sodium Saccharin, Sucralose | None | Sweeteners are not used in the subject device. |
| **Conditions of Use** | | | |
| **Area of Use** | Oral cavity | Oral cavity | Same |
| **Dosage Form** | Oral rinse | Oral rinse | Same |
| **Dosage (per use)** | 20 mL (4 teaspoons) | 1g dissolved in 20 mL water. | Same |
| **Applications/Day** | Up to 2 times daily. | As often as needed. | Similar |
| **Method of Use** | Ready to use liquid. | Powder to be mixed with $H_2O$ prior to use. | Similar, both are in liquid form when used. |
| **Environment of Use** | Home | Home | Same |
| **Prescription/OTC** | OTC | $R_x$ | The subject device is sold by prescription to maintain its prescribed storage condition and product integrity while it remains at the pharmacy prior to being sold to the end user. |
| **Packaging Unit** | 8/16/33.8 fl-oz bottles | 30 (1g) packets / box Dissolution Bottle | Similar. The differences between the way the subject and predicate devices are packaged is a function of their physical state. |
| **Physical Properties (Performance Testing)** | | | |
| **Appearance** | Viscous liquid, when applied | Viscous liquid, when applied | Same |

| | | | |
|---|---|---|---|
| **pH** | 5.91 | 7.29 | Similar. The subject and predicate devices have pH values near the pH of saliva (5.3 - 7.8). |
| **Viscosity (Pa-s)** | 0.0126 | 0.0019 | Similar. The values are not significantly different when compared to the viscosity of the saliva (0.0078 Pa-s). |
| **Surface Tension (dyn/cm)** | 30.24 | 49.28 | Similar. The values are not significantly different when compared to the surface tension of saliva (58 dyn/cm). |
| **Moisturization/Hydration of Cell** | 12.0±3.38% | 71.9±47.26% | Similar. The difference is not statistically significantly different in protecting epithelial cells from dryness (p-value = 0.093). |
| **Sterility** | Non-Sterile | Non-Sterile | Similar. |
| **Shelf-Life** | 24 months | 18 months | Similar. The validated shelf-life of the subject device is 18 months when stored as instructed. |
| **Storage Condition** | Not specified | -20±5 °C (-4 ± 9°F) | The subject device is stored under the prescribed storage condition to maintain the integrity (stability) of the product. |
| **Biocompatibility Testing** | | | |
| **Biocompatibility** | Conforms with ISO 10993-1<br>• cytotoxicity<br>• sensitization<br>• irritation | Conforms with ISO 10993-1<br>• cytotoxicity<br>• sensitization<br>• irritation | Same |

## 9. Non-Clinical Performance Data

As part of demonstrating substantial equivalence of MucoPEG™ to the predicate device, SunBio submitted the subject device for testing in accordance with the applicable parts of the following voluntary standards:

- ISO 10993-5 (cytotoxicity)
- ISO 10993-10 (irritation)
- ISO 10993-10 (sensitization)

SunBio also performed various physical properties tests on MucoPEG™ in a side-by-side manner against the predicate device for certain performance characteristics that are relevant to artificial saliva products. These tests included:

- Appearance
- pH
- Viscosity
- Surface Tension
- Moisturization/Hydration of cultured epithelial layer cells

## 10. Statement of Substantial Equivalence

MucoPEG™ artificial saliva has the same intended use and indications for use, and similar technological features as Hydris™ Oral Rinse. Any minor differences in the ingredients used to make the subject device when compared to the predicate device have been successfully evaluated by SunBio through side-by-side comparative testing of the physical properties of the two devices, as well as by biocompatibility testing on the subject device, such that the information submitted to the FDA demonstrates that the subject device, when compared to the predicate device, does not raise any new questions of safety and effectiveness. MucoPEG™ artificial saliva, as designed and manufactured by SunBio, has been determined to be substantially equivalent to Hydris™ Oral Rinse.