March 19, 2018

Syendgen, Inc.
Christopher Ryan, Ph.D.
Director of Manufacturing
1420 N. Claremont Blvd. Suite 105D
Claremont, California 91711

Re: K173237
Trade/Device Name: Moisyn Dry Mouth Oral Rinse, Moisyn Dry Mouth Oral Mist, Moisyn Free Dry Mouth Oral Rinse, Moisyn Free Dry Mouth Oral Mist
Regulatory Class: Unclassified
Product Code: LFD
Dated: February 15, 2018
Received: February 16, 2018

Dear Christopher Ryan:

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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173237

Device Name
Moisyn Dry Mouth Oral Rinse, Moisyn Dry Mouth Oral Mist, Moisyn Free Dry Mouth Oral Rinse, Moisyn Free Dry Mouth Oral Mist

Indications for Use *(Describe)*
Relieves the symptoms of dry mouth, while moisturizing and lubricating 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.

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510(k) Summary K173237

Synedgen, Inc.

Moisyn Dry Mouth Oral Rinse, Moisyn Dry Mouth Oral Mist,
Moisyn Free Dry Mouth Oral Rinse, Moisyn Free Dry Mouth Oral Mist

Submitter:

Synedgen, Inc.
1420 North Claremont Blvd, Suite 105D
Claremont, CA 91711
Phone: 909-447-6858
Fax: 909-447-6801
Contact Person: Shenda Baker
Correspondent: Christopher Ryan
Date Prepared: March 19, 2018

Device:

Name of Device: Moisyn Dry Mouth Oral Rinse, Moisyn Dry Mouth Oral Mist,
Moisyn Free Dry Mouth Oral Rinse, Moisyn Free Dry Mouth Oral Mist
Common or Usual name: Dry Mouth Spray
Artificial Saliva
Classification: Unclassified
Product Code: LFD

Primary Predicate Device:

Dr. Fresh Dry Mouth Mouthwash K111250 (LFD)
This predicate has not been subject to a design-related recall.

Reference Predicate Devices:

Oasis Dry Mouth(K041563), Moi-Stir(K810157), SynePure (K143444), Oral 7 Moisturizing Mouth Spray(K142549), Mouth Kote Oral Moisturizer (K062653)

Device Description:

Moisyn is a specifically formulated artificial saliva substitute which contains moisturizers, humectants, and biopolymers that are designed to relieve dry mouth symptoms, soothe irritated oral surfaces, refresh, clean, and lubricate.

The rinse is supplied as an 8oz PET bottle or as a 2oz PET spray bottle. Both bottles contain the same solution without any changes in formulation or intended use.

Both the rinse and the Mist are formulated with and without spearmint flavor to provide the customer with a choice in flavoring.

Indications for use:

Relieves the symptoms of dry mouth, while moisturizing and lubricating oral dryness.

Comparison with predicate:

The candidate device, Moisyn, has the same intended use and the substantially equivalent technological characteristics as the predicate device: Dr. Fresh Dry Mouth Mouthwash. Both the predicate and the proposed device are aqueous based solutions that use neutral sugars (glycerol and sorbitol) as well as polymers to assist in the moisturizing dry mouth. The proposed device and predicate use sorbitol to balance the solution and to provide a denser solution. The proposed device and predicate are preserved to control microbial content. The proposed device and predicate are delivered with a pH that is not significantly acidic or basic. Like the predicate device, Moisyn acts as an artificial saliva that utilizes moistening properties to aid in the moisturizing and lubricating of oral dryness.

Comparison of New and Predicate Devices

	New Device (Moisyn)	**Predicate Device (Dr. Fresh)**
Intended Use	Symptomatic treatment of Xerostomia (Dry Mouth)	Symptomatic treatment of Xerostomia
Indications for Use	Relieves the symptoms of dry mouth, while moisturizing and lubricating oral dryness.	Relieves the symptoms of dry mouth, while moisturizing and lubricating oral dryness.
Sterile or preservative	Non-sterile, preserved	Non-sterile, preserved
Composition	Purified water Sorbitol Xylitol Glycerol Chitosan derivatives Betaine Flavor Sodium Hydroxide for pH balance	Purified water Sorbitol Xylitol Propylene Glycol Poloxamer 407 Polyvinylpyrrodlidone Sodium Benzoate Benzoic Acid Flavor Menthol Calcium lactate Zinc Gluconate Aloe Vera Sodium Phosphate Bactase Oral
Delivery	Oral Cavity via PET bottle with removable cap or PET bottle with nozzle spray	Oral Cavity via PET bottles with flip caps
Mode of action	Moisturizing and lubricating oral dryness	Moisturizing and lubricating oral dryness
Type of Product	Liquid Solution	Liquid Solution
pH	5.5 – 8.0	5.3

The proposed device has substantially equivalent technological characteristics as a non-sterile, preserved, non-toxic, polymer-based mouthwash and is similar in design and configuration to the

predicate device. The proposed device is designed and assembled with components found in the predicate and reference devices.

Performance data:

Biocompatibility Testing

Moisyn has been tested in accordance with ISO 10993 and was shown to meet the requirements of biocompatibility testing for Cytotoxicity, Maximization Test for Delayed-Type Hypersensitivity, Dermal Irritation, Oral Mucosal Irritation, and Acute Systemic Toxicity.

Test	**Description**	**Result**
Cytotoxicity Direct Contact	Cytotoxicity was evaluated using ISO-10993-5, Biological evaluation of Medical Devices-Part 5: *Tests for In Vitro Cytotoxicity*.	Non-toxic
Maximization Test for Delayed-Type Hypersensitivity	The ability of Moisyn Oral Rinse/Mist to cause delayed-type hypersensitivity was evaluated according to ISO 10993-10:2010, *Biological evaluation of medical devices – Part 10: Tests for Irritation and skin sensitization.*	No Sensitization reaction was observed in any of the test animals
Dermal Irritation	To assess dermal irritation due to exposure of skin to Moisyn Oral Rinse and Mist, the test articles was evaluated according to ISO 10993-10:2010, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.*	No erythema or edema (score of 0) was observed on test sites at the 1, 24, 48, and 72-hour scoring. The Primary Irritation Index for the test article was 0.
Oral Mucosal Irritation	To assess oral mucosal irritation due to exposure to Moisyn Oral Mist, the test article was evaluated according to ISO 10993-10:2010, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.*	The Oral Irritation Index for the test article was 0.0.
Acute Systemic Toxicity	To assess the acute systemic toxicity of the Moisyn Oral Mist, which was tested according to ISO 10993-11, *Biological Evaluation of Medical Devices – Tests for Systemic Toxicity.*	The test article met the requirements for the Acute Systemic Toxicity Test and the requirements of ISO 10993-11

Preservative Effectiveness

The Moisyn Dry Mouth Oral Rinse/Mist was tested for its preservative effectiveness. The data indicate that Moisyn Dry Mouth Oral Rinse/Mist meet the requirements of USP 51.

Shelf-Life

The stability data indicate the product meets specifications after two years of storage and is scheduled to test up to 3 years.

Viral Inactivation

Viral inactivation was assessed.

Clinical Study

An initial study of 57 patients with Xerostomia was conducted to treatment with Moisyn. Substantial equivalence is based in part on this study. Statistically significant improvements in dry mouth symptoms, reduction in oral pain, and improvement in taste/diet were demonstrated. Whole unstimulated/resting saliva and whole stimulated saliva improved.

Epstein, Joel B, Dana C Villines, Mabi Singh, and Athena Papas. 2017. *"Management of dry mouth: assessment of oral symptoms after use of a polysaccharide-based oral rinse."* Oral Medicine 76-83

Conclusions:

Based on the Indications for Use and the data presented in this submission, Moisyn is substantially equivalent to the predicate device Dr. Fresh Dry Mouthwash (K111250).