May 27, 2020

Christopher Ryan, COO
Synedgen, Inc.
1420 North Claremont Blvd. Suite 105D
Claremont, California 91711

Re: K193336
Trade/Device Name: Synvaza Mouth Sore and Wound Rinse, Synvaza II Mouth Sore and Wound Rinse
Regulatory Class: Unclassified
Product Code: OLR, MGQ
Dated: April 29, 2020
Received: April 30, 2020

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. 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 “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

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)*
K193336

Device Name
Synvaza Oral Wound Rinse

Indications for Use *(Describe)*
Synvaza manages the pain in many types of oral wounds, mouth sores, injuries, and ulcers of the oral mucosa. It adheres to oral tissue and forms a protective barrier between the wound and further irritation and contamination. It provides the moist wound environment required for optimal wound healing. Manages pain associated with oral wounds, mouth sores, injuries and ulcers of the mouth such as: canker sores, irritation and traumatic ulcers; aphthous ulcers.

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 K193336

Synedgen, Inc.

Synvaza and Synvaza II

Submitter:

Synedgen, Inc.
1420 North Claremont Blvd, Suite 105D
Claremont, CA 91711
Phone: 909-447-6858
Fax: 909-447-6801
Contact Person: Christopher Ryan
Date Prepared: May 23, 2020

Device:

Name of Device: Synvaza and Synvaza II

Common or Usual name: Dressing, wound and burn, hydrogel w/drug and/or biologic

Classification: Unclassified

Product Code: MGQ

Primary Predicate Device:

"Sock It!" Oral Pain Gel (K063148)

Reference Predicate Devices:

Gengigel Rinse (K053342)
Moisyn (K173237)

Device Description:

Synvaza is an oral wound rinse specifically formulated with moisturizers, humectants, and mucoadhesive biopolymers that are designed to manage the pain in many types of oral wounds, mouth sores, injuries, and ulcers of the oral mucosa. When swished around the mouth, the mucoadhesive formulation results in a temporary formation of a protective coating over the oral mucosa. The liquid also provides a moist wound environment, which is required for optimal wound healing.

Synvaza is supplied in plastic bottles with and without a hand pump.

Indications for Use:

Synvaza manages the pain in many types of oral wounds, mouth sores, injuries, and ulcers of the oral mucosa. It adheres to oral tissue and forms a protective barrier between the wound and further irritation and contamination. It provides the moist wound environment required for optimal wound healing. Manages pain associated with oral wounds, mouth sores, injuries and ulcers of the mouth such as: canker sores, irritation and traumatic ulcers; aphthous ulcers.

Comparison of Technology:
Both the predicate and proposed devices are aqueous-based formulas that contain polysaccharides to form films on the mucosal surface and protect it from irritation. Like the predicate, Synvaza contains mucoadhesive film formers, chitosan derivatives, which adhere to oral tissues and form a protective barrier between wounds and further irritation or contamination. Like the predicate, the ingredients in Synvaza, chitosan derivatives in combination with glycerol and sorbitol, provide a moist wound environment required for optimal wound healing.

The non-substantial difference in design between Synvaza and Gengigel in comparison to "Sock it!" gel is the time at which water is incorporated. With Synvaza and Gengigel, the water is incorporated at the factory when the product is made. With "Sock it!", the water is incorporated in the mouth with saliva. Synvaza, Gengigel, and "Sock It!" all adhere to the surface of the wound surface and provide a barrier to manage pain.

Non-clinical Performance Testing:
Biocompatibility and preservative data were collected to show equivalence in safety of the product. A clinical study shows equivalence in efficacy.

Biocompatibility Testing

Test	**Result**
Cytotoxicity	Not Cytotoxic
Maximization test for delayed-type hypersensitivity	Not Sensitizing
Dermal irritation	Not irritating to dermal tissue
Oral mucosal irritation	Not irritating to oral tissue
Acute systemic toxicity	Not systemically toxic

Preservation

Synvaza meets the challenges tested based on USP <51> "Category 3" for aqueous products that are used in the oral cavity.

Clinical Performance Testing:

In an open label, single arm study of preselected study subjects who used your proposed device at least twice a day for 72 hours, study subjects reported experience of pain relief for the study duration.

Conclusions:

The candidate device, Synvaza, is substantially equivalent to the predicate device, "Sock It!" Gel (K063148). Synvaza has the same intended use, indications for use, and substantially equivalent technological characteristics as the predicate device.

Based upon similarities in the Indications for Use as well as technology, together with the results of non-clinical and clinical performance testing, we conclude that Synvaza and Synvaza II are substantially equivalent to the predicate device K063148.