November 20, 2020

Sa3, LLC
% Daniel Schultz
Principal, Devices and Combination Products
Greenleaf Health, Inc.
1055 Thomas Jefferson Street, NW, Suite 450
Washington, District of Columbia 20007

Re: K202000
Trade/Device Name: Silatrix Oral Gel
Regulatory Class: Unclassified
Product Code: OLR, FRO
Dated: August 31, 2020
Received: September 1, 2020

Dear Dr. Daniel Schultz:

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

Statement of Indications for Use (FDA Form 3881)

Indications for Use

510(k) Number (if known): K202000

Device Name: Silatrix Oral Gel

Indications for Use:

Silatrix Oral Gel forms a protective layer over the oral mucosa by adhering to the mucosal surface which allows it to protect against further irritation and relieve pain. The oral gel may be used in the management of mouth lesions including aphthous ulcer, stomatitis, mucositis, minor lesions, chafing and traumatic ulcers, abrasions caused by braces and ill-fitting dentures, and lesions associated with oral surgery.

Prescription Use ___**X**____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

SA3, LLC
2317 Cotner Avenue
Los Angeles, CA 90064-1803
TEL 888.495.6078
FAX 888.502.1669
INFO info@SA3pharma.com

510(k) SUMMARY K202000

Silatrix Oral Gel

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

SA3, LLC
2317 Cotner Avenue
Los Angeles, CA 90064
Phone: 310.282.8086
Fax: 888.502.1669
Contact Person: Farbod Melamed, Pharmacist

Date Prepared: 11/20/20

Name of Device and Name/Address of Sponsor

Silatrix Oral Gel
SA3, LLC
2317 Cotner Avenue
Los Angeles, CA 90064

Common or Usual Name

Polymerized cross-linked sucralfate gel treatment

Classification Name

Product Code: OLR, FRO
Unclassified
Oral Wound Dressing, Dressing, Wound, Drug

Primary Predicate

K-Number: K123904
Common or Usual Name: Sucralfate Malate Paste
Trade/Proprietary/Model Name: ProThelial & Orafate Sucralfate Paste
Classification Name: Dressing, Wound, Drug
Product Code: FRO
Classification: Unclassified
Applicant: Mueller Medical International LLC

Reference Device

K-Number: K193336
Common or Usual Name: Synvaza and Synvaza II
Classification Name: Dressing, Wound And Burn, Hydrogel W/Drug And/Or Biologic
Product Code: MGQ
Classification: Unclassified
Applicant: Synedgen, Inc.

Device Description

The proposed Silatrix Oral Gel is an amorphous hydrogel formed by the controlled reaction of sucralfate with a limited quantity of malic acid and calcium carbonate solution. The amorphous hydrogel formed by this reaction binds reversibly to wounds and is intended to form a protective film that covers wounds, protects against further irritation and relieves pain. The intended use of this device is achieved by physical action. Silatrix Oral Gel may be administered directly to an accessible oral wound to provide an adherent physical covering of the wound bed. Although prepared by the reaction of sucralfate with an acid, the polymerized sucralfate self-buffers to a pH 5.0 - 7 .0, the subject device achieves its primary mode of action through serving as a physical barrier for temporary protection of oral mucosal tissue and to provide pain relief. There is no chemical action or metabolic effect associated with the mechanism of action of this device.

Silatrix Oral Gel contains sucralfate, malic acid, calcium carbonate, calcium sulfate dihydrate, sucralose, xanthan gum, propylene glycol, and purified water. Silatrix Oral Gel, which is labeled for prescription use only, is supplied non-sterile in a small tube.

Indications for Use

Silatrix Oral Gel forms a protective layer over the oral mucosa by adhering to the mucosal surface which allows it to protect against further irritation and relieve pain. The oral gel may be used in the management of mouth lesions including aphthous ulcer, stomatitis, mucositis, minor lesions, chafing and traumatic ulcers, abrasions caused by braces and ill-fitting dentures, and lesions associated with oral surgery.

Nonclinical Performance Data

Non-clinical performance data relied on in this determination of substantial equivalence demonstrate the identical nature of the clinically effective component of the Silatrix Oral Gel and its predicate device, the ProThelial & Orafate Sucralfate Paste. The clinically effective component is sucralfate USP, without which neither device would function. The non-clinical tests involved those required by USP national standards to verify the presence of sucralfate. The sucralfate used in each of the devices is an o-D-glucopyranoside, P- Dfructofuranosyl-, octakis-(hydrogen sulfate), aluminum complex, molecular weight of 2,086.75.

Biocompatibility testing was conducted for the proposed device. As the proposed device is an amorphous hydrogel for topical use in oral mucosa, all components of the device are considered direct contact components. Cytotoxicity, Sensitization and Irritation testing was conducted. The results showed that the Silatrix Oral Gel is not considered to be cytotoxic and not considered to be a contact skin sensitizer or an oral irritant. Shelf life testing was also conducted for the proposed device.

Substantial Equivalence

The proposed Silatrix Oral Gel has the same intended use as its primary predicate device, namely to serve as a physical barrier on oral mucosal tissues, to protect against further irritation and manage or relieve pain. In addition, the proposed Silatrix Oral Gel features identical indications for use language, similar technological characteristics and principles of operation.

The minor technological difference between these two devices is in the dosage form and excipients. The proposed device, the Silatrix Oral Gel and its primary predicate, the ProThelial & Orafate Sucralfate Paste are described as a gel and paste respectively, which are still viscous aqueous gel formulations. Both devices are semisolid for topical application and are free of fatty vehicles. As per FDA's definitions of gel and paste, the dosage form gel describes the Silatrix Oral Gel better than the paste. The differences in the technological characteristics between closely related paste and gel dosage forms for topical application do not raise new questions of safety or effectiveness. However, to further support the substantial equivalence of the proposed device, a reference device was introduced to capture the hydrogel technology featured in the proposed device. Reference device Synvaza (and Synvaza II) is also an oral wound dressing available in a hydrogel formulation, just as found in the proposed Silatrix Oral Gel.

Substantial Equivalence Chart			
Device Number	**K202000**	**K123904**	**K193336**
Product Name	**Silatrix Oral Gel (Proposed Device)**	**ProThelial & Orafate Sucralfate Paste**	**Synvaza and Synvaza II**
Applicant	SA3, LLC	Mueller Medical International LLC	Synedgen, Inc.
Classification Name	Dressing, Wound and Burn, Hydrogel W/Drug and/or Biologic	Dressing, Wound, Drug	Dressing, Wound and Burn Hydrogel W/ Drug and/or Biologic
Classification	Unclassified	Unclassified	Unclassified
Product Code	OLR, FRO	FRO	OLR, FRO
Type	Rx Medical device	Rx Medical Device	OTC Medical Device
Patient Group	Pediatric & Adult	Pediatric & Adult	Pediatric & Adult

Ingredients	Sucralfate, malic acid, calcium carbonate, xanthan gum, calcium sulfate dihydrate, purified water, sucralose, propylene glycol	Sucralfate, malic acid, calcium carbonate, xanthan gum, calcium sulfate, purified water, methyl parabens, propyl parabens, sodium saccharin	Water, sorbitol, glycerin, betaine, (benzoic acid- Synvaza II) chitosan derivatives, sodium hydroxide
No. Application per Day	Apply to mucosal wounds 2 to 3 times daily.	Application to mucosal wounds 2 -3 times daily.	Swish 1-3 teaspoons of rinse in mouth for 1 minute and spit out; use up to 10 times daily.
Claim	Management and relief of pain, does not sting, nonirritating, safe if swallowed.	Management and relief of pain, non- irritating, safe if swallowed.	Management of pain and maintenance of a moist wound environment.
Mechanism of Action	Amorphous hydrogel binds reversibly to wounds and is intended to form a protective film that covers wounds, protects against further irritation and relieves pain.	Device binds reversibly to wounds to form a protective film where local wound bed acidity is not available or present on oral mucosa. Provides an adherent physical covering of the wound bed.	Polysaccharide polymer from a natural source that adheres to oral mucosa and protects it from irritation by forming a protective barrier. It also creates a moist wound environment, which is necessary for the natural healing process.
Intended Use	Form a protective film that covers oral wounds, protects against further irritation and relieves pain	Form a protective film over oral mucosal wounds; relieves pain.	Management of pain and maintenance of a moist wound environment.
Indication	Silatrix Oral Gel forms a protective layer over the oral mucosa by adhering to the mucosal surface which allows it to protect against further irritation and relieve pain. The oral gel may be used in the management of mouth lesions including aphthous ulcer, stomatitis, mucositis, minor lesions, chafing and traumatic ulcers, abrasions caused by braces and ill-fitting dentures, and lesions associated with oral surgery	ProThelial™ & Orafate Sucralfate Malate Paste forms a protective layer over the oral mucosa by adhering to the mucosal surface which allows it to protect against further irritation and relieve pain. The paste may be used in the management of mouth lesions of all types including aphthous ulcer, stomatitis, mucositis, minor lesions, chafing and traumatic ulcers, abrasions caused by braces and ill-fitting dentures, and lesions associated with oral surgery.	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.
Description	Silatrix Oral Gel is an amorphous hydrogel formed by the controlled reaction of sucralfate with a limited quantity of malic acid and calcium carbonate solution. The amorphous hydrogel formed by this reaction binds reversibly to wounds and is intended to form a protective film that covers	ProThelial & Orafate Sucralfate Paste is an amorphous hydrogel paste formed by the controlled reaction of sucralfate with a limited quantity of malic acid and calcium carbonate solution. The amorphous hydrogel paste formed by this reaction binds reversibly to wounds and is intended to	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

	wounds, protects against further irritation and relieves pain. Silatrix Oral Gel may be administered directly to an accessible oral wound to provide an adherent physical covering of the wound bed. Although prepared by reaction of sucralfate with an acid, the polymerized sucralfate self-buffers to a pH 5.0 - 7 .0.	form a protective film that covers wounds, protects against further irritation and relieves pain. ProThelial"' & Orafate Sucralfate Paste may be administered directly to an accessible oral wound to provide an adherent physical covering of the wound bed. Although prepared by reaction of sucralfate with an acid, the polymerized sucralfate self-buffers to a pH 5.0 - 7 .0.	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.
Area of Use	Oral Mucosa	Oral Mucosa	Oral Mucosa
Type of Product	Gel	Paste	Gel
Presentation	Non-Sterile	Non-Sterile	Non-Sterile

Conclusions:

The Silatrix Oral Gel and the predicate device, the ProThelial & Orafate Sucralfate Paste, have the same intended use and similar indications, technological characteristics and principles of operation. The only technological difference between the Silatrix Oral Gel and its predicate is the difference in dosage form and excipients. As explained above, these differences do not present any new issues of safety or effectiveness. The performance data also demonstrates the identical nature of the sucralfate component in these two devices. Thus, the Silatrix Oral Gel is substantially equivalent to the ProThelial & Orafate Sucralfate Paste.