October 23, 2025

Sa3, LLC
% Mark Kramer
Principal, Medical Devices & Combination Products
Eliquent Life Sciences, Inc.
1055 Thomas Jefferson St., Suite 450
Washington, District of Columbia 20007

Re: K252425
Trade/Device Name: Silatrix Oral Gel
Regulatory Class: Unclassified
Product Code: OLR
Dated: August 1, 2025
Received: August 1, 2025

Dear Mark Kramer:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252425

Device Name
Silatrix Oral Gel

Indications for Use *(Describe)*
Silatrix Oral Gel forms a protective layer over the oral

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.

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

K252425

Silatrix Oral Gel

Submitter's Contact Information 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/Regulatory Compliance

Date Prepared: August 1, 2025

Name/Address of Sponsor
Silatrix Oral Gel
SA3, LLC
2317 Cotner Avenue
Los Angeles, CA 90064

Name of Device
Silatrix Oral Gel

Common or Usual Name
Oral Wound Dressing

Classification Information
Class: Unclassified
Product Code: OLR
Product Code Description: Oral Wound Dressing

Predicate Device
510(k) Number: K202000
Trade/Proprietary/Model Name: Silatrix Oral Gel
Common/Usual Name: Oral Wound Dressing
Product Code: OLR, FRO
Class: Unclassified
Applicant: SA3, LLC

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Device Description

Silatrix Oral Gel is an amorphous hydrogel that serves as a physical, protective barrier over the oral mucosa to protect against further irritation and relieve pain associated with mouth lesions. The hydrogel is formed during manufacturing by the controlled reaction of sucralfate with a limited quantity of malic acid and calcium carbonate solution.

Silatrix Oral Gel contains sucralfate, malic acid, calcium carbonate, calcium sulfate dihydrate, sucralose, xanthan gum, propylene glycol, and purified water, as well as pentylene glycol and glycerin-ethyl lauroyl arginate HCl that are used as preservatives. Silatrix Oral Gel, which is labeled for prescription use only, is supplied non-sterile in a 10g tube.

The formulation is identical to the predicate device except for the addition of the two preservatives used to ensure device stability over the labeled shelf life.

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.

The indications for use are identical to the predicate device, which is the original formulation of Silatrix Oral Gel cleared under K202000. Likewise, its intended use as a protective barrier oral wound dressing is identical to the predicate device.

Substantial Equivalence

The following table compares the similarities and differences of the subject and predicate devices.

Characteristic	Subject Device (Present Submission)	Predicate Device (K202000)	Comparison
510(k) Number	(Unassigned)	K202000	N/A
Product Code	OLR	OLR; FRO	Identical except for the removal of product code FRO assigned to the original 510(k)

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			(wound dressing with drug). It is not applicable to either the subject or predicate devices as Silatrix Oral Gel contains no drug component. Sucralfate is a device when used as an oral protective barrier. See publicly available FDA RFD decision from 2004 for similar device.
Product Code Name	Oral Wound Dressing	Oral Wound Dressing	Identical
Classification	Unclassified	Unclassified	Identical; oral wound dressing is an unclassified pre-Amendments device
Description	Like other 510(k) cleared oral wound dressings, including the predicate device, Silatrix Oral Gel works by serving as a physical, protective barrier over the oral mucosa to protect against further irritation and relieve pain associated with mouth lesions. Identical to the predicate device, the subject device is an amorphous hydrogel formed during manufacturing by the controlled reaction of	Like other 510(k) cleared oral wound dressings, including the predicate device, Silatrix Oral Gel works by serving as a physical, protective barrier over the oral mucosa to protect against further irritation and relieve pain associated with mouth lesions. Identical to the predicate device, the subject device is an amorphous hydrogel formed during manufacturing by the controlled reaction of	Identical

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	sucralfate with a limited quantity of malic acid and calcium carbonate solution.	sucralfate with a limited quantity of malic acid and calcium carbonate solution.	
Ingredients	Sucralfate, malic acid, calcium carbonate, xanthan gum, calcium sulfate dihydrate, purified water, sucralose, propylene glycol, glycerin-ethyl lauroyl arginate HCl, and pentylene glycol	Sucralfate, malic acid, calcium carbonate, xanthan gum, calcium sulfate dihydrate, purified water, sucralose, and propylene glycol,	Identical except for the addition of glycerin-ethyl lauroyl arginate HCl and pentylene glycol as preservatives to ensure microbial stability over the device shelf life.
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.	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.	Identical
Applications/Day	Apply to mucosal wounds 2-3 times daily	Apply to mucosal wounds 2-3 times daily	Identical

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Area of Use	Oral mucosa	Oral Mucosa	Identical
Product Form	Gel	Gel	Identical
Sterility	Non-sterile	Non-sterile	Identical
Patient Population	Adults & Pediatrics	Adults & Pediatrics	Identical
Prescription Use	Prescription Use	Prescription Use	Identical
Packaging	10 g tube	10 g tube	Identical

The subject and predicate devices are identical in all respects except for the addition of the two preservatives (glycerin-ethyl lauroyl arginate HCl and pentylene glycol) to ensure microbial stability over the labeled shelf life. To account for the addition of the preservatives to the formulation, the quantity of purified water has been slightly reduced. Following the inclusion of the two preservatives, there were no changes to the device's physical or chemical attributes.

The addition of preservatives to ensure device stability do not raise different questions of safety or effectiveness in comparison to the predicate device. Stability is a key question for most medical devices, including the subject and predicate devices.

Performance Testing

Comprehensive biocompatibility, stability/shelf life, and antimicrobial preservative efficacy testing was conducted to confirm product conformance with device requirements and substantially equivalent performance as the predicate device. Key performance data demonstrated the device meets its performance specifications over the labeled shelf life and the antimicrobial efficacy of the preservatives added to the formulation. The key studies summarized below demonstrate that the device is as safe, as effective, and performs as well or better than the legally marketed predicate device.

Biocompatibility Testing

Biocompatibility testing was conducted in accordance with ISO 10993. The same biocompatibility testing conducted to support the original clearance of K202000 was repeated for the final, finished reformulated device (i.e., with the two new preservative ingredients). Identical to the predicate device 510(k) submission, this testing included cytotoxicity, sensitization, and oral mucosal irritation testing.

All three studies met the established success criteria. The test article was not considered cytotoxic according to the direct cell contact method; it was not considered to be an irritant to the oral mucosa of Golden Syrian hamsters; and it was not considered to be a contact sensitizer in the guinea pig.

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Shelf Life and Antimicrobial Preservative Efficacy Testing

Shelf life and antimicrobial efficacy testing were conducted to demonstrate that the addition of the two preservatives had the intended effect in ensuring device stability and that the reformulated device met its specifications.

Accelerated and real-time stability studies were conducted. All evaluated attributes (description, pH, water content, assay, and microbial enumeration) met requirements for all time points for both accelerated and real-time testing, thus demonstrating stability over the intended shelf life.

In addition, a USP Antimicrobial Preservative Efficacy Study was conducted. This study, conducted to USP methods, evaluated preservative efficacy against *e. coli, pseudomonas aeruginosa, staphylococcus aureus, candida albicans, and aspergillus brasiliensis* at 14 days and 28 days. All criteria were met, thus demonstrating that the product complies with the USP requirements for antimicrobial preservative effectiveness.

Conclusions

The biocompatibility, stability/shelf life, and USP antimicrobial preservative efficacy studies concluded that the subject device is biocompatible; maintains product specifications and stability over the labeled shelf life; and has substantially equivalent performance to the predicate device with respect to meeting the specifications established for its intended use. These results demonstrate that Silatrix Oral Gel is as safe, as effective, and performs as well or better than the legally marketed predicate device.

In summary, Silatrix Oral Gel is substantially equivalent to the predicate formulation of the same device with respect to intended use, technological characteristics and performance. The biocompatibility, stability/shelf life and antimicrobial preservative efficacy studies demonstrate that the device is as safe, as effective, and performs as well or better than the legally marketed predicate device.