June 15, 2026

USpharma, Ltd.
% Samantha Eakes
Vice President, Regulatory Affairs
Eliquent Life Sciences, Inc.
1055 Thomas Jefferson St., Suite 450
Washington, District of Columbia 20007

Re: K260126
Trade/Device Name: Curajel™ Oral Gel
Regulatory Class: Unclassified
Product Code: OLR
Dated: May 11, 2026
Received: May 11, 2026

Dear Samantha Eakes:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260126

Please provide the device trade name(s).

Curajel™ Oral Gel

Please provide your Indications for Use below.

Curajel™ Oral Gel is intended for use as an oral wound dressing to protect ulcer tissue by forming a physical barrier on the wound tissue to avoid further irritation and thus to relieve pain. It is indicated for use with all types of ulcers and small wounds of the oral mucosa including canker sores, aphthous ulcers, and injuries such as traumatic ulcers caused by self-biting, braces, and ill-fitting dentures.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY K260126
Curajel™ Oral Gel

Submitter's Contact Information and Date Prepared

USpharma, Ltd.
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Contact Person: Rushi Patel, Vice President Manufacturing and Regulatory

Date Prepared: May 11, 2026

Name/Address of Sponsor

Curajel™ Oral Gel
USpharma Ltd.
Miami Lakes, FL, 33014

Name of Device

Curajel™ 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: K183436
Trade/Proprietary/Model Name: OraCure
Common/Usual Name: Oral Wound Dressing
Product Code: OLR
Class: Unclassified
Applicant: TBM Corporation

Reference Device

510(k) Number: K252425
Trade/Proprietary/Model Name: Silatrix Oral Gel

Common/Usual Name: Oral Wound Dressing
Product Code: OLR
Class: Unclassified
Applicant: SA3, LLC

Device Description

Curajel™ 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 wounds. The hydrogel is formed during manufacturing by the controlled reaction of sucralfate with a limited quantity of malic acid and calcium carbonate solution.

Curajel™ 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. Curajel™ Oral Gel, which is labeled for over-the-counter use, is supplied non-sterile in a 10g tube.

Indications for Use

Curajel™ Oral Gel is intended for use as an oral wound dressing to protect ulcer tissue by forming a physical barrier on the wound tissue to avoid further irritation and thus to relieve pain. It is indicated for use with all types of ulcers and small wounds of the oral mucosa including canker sores, aphthous ulcers, and injuries such as traumatic ulcers caused by self-biting, braces, and ill-fitting dentures.

Substantial Equivalence

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

Characteristic	Subject Device (Present Submission)	Predicate Device	Reference Device	Comparison
510(k) Number	K260126	K183436	K252425	N/A
Name	Curajel™ Oral Gel	OraCure	Silatrix Oral Gel	N/A
Product Code	OLR	OLR	OLR	Identical
Product Code Name	Oral Wound Dressing	Oral Wound Dressing	Oral Wound Dressing	Identical
Classification	Unclassified	Unclassified	Unclassified	Identical; oral wound dressings are an unclassified pre-Amendments device.

Characteristic	Subject Device (Present Submission)	Predicate Device	Reference Device	Comparison
Description	Curajel™ 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 wounds. The device is an amorphous hydrogel formed during manufacturing by the controlled reaction of sucralfate with a limited quantity of malic acid and calcium carbonate solution. It has a pH of 5.0-7.0.	OraCure® is a vacuum-dried gel that adheres to oral mucosa. It slowly reverts to a soft and gel-type thin sheet in the oral environment while it adheres to and protects affected tissue as a physical barrier to reduce irritation and pain.	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. The device is an amorphous hydrogel formed during manufacturing by the controlled reaction of sucralfate with a limited quantity of malic acid and calcium carbonate solution. It has a pH of 5.0-7.0.	The subject and the predicate devices are similar in design as each is a gel-type wound dressing that creates a physical barrier to protect the oral mucosa and relieve irritation and pain. The subject and the reference device are identical in all technological aspects and formulation.
Ingredients	Sucralfate, malic acid, calcium carbonate, xanthan gum, calcium sulfate dihydrate, purified water, sucralose, propylene glycol, glycerin-ethyl lauroyl arginate HCl, and pentylene glycol	Not available in 510(k) summary or other publicly available information	Sucralfate, malic acid, calcium carbonate, xanthan gum, calcium sulfate dihydrate, purified water, sucralose, propylene glycol, glycerin-ethyl lauroyl arginate HCl, and pentylene glycol	Ingredients for the predicate device are not publicly available. The ingredients and formulation are identical between the subject and the reference device.
Specifications	Description: White gel pH: Between 5 to 7 Water Content by KF: Not less than 55.0%	D: Diameter, T: Thickness W: Wide, L: Length	Description: White gel pH: Between 5 to 7 Water Content by KF: Not less than 55.0%	The subject device which is applied in gel form is similar to the predicate device which forms a gel-like sheet after exposure to moisture in the mouth environment.

Characteristic	Subject Device (Present Submission)	Predicate Device	Reference Device	Comparison
	Assay: 90.0%-110.0% of the labeled amount Total Aerobic Microbial Count: NMT 10^2 cfu/g Total Yeast and Mold Count: NMT 10^1 cfu/g Staphylococcus aureus: Absent Pseudomonas aeruginosa: Absent	① Model No.: CR12 - Circle Shape (DxT) 1.2cm x (0.3~0.399)mm ② Model No.: OB23 - Rectangle Shape (WxLxT) 2.5cm x 15mm x (0.3~0.399)mm ③ Model No.: OB25 - Rectangle Shape (WxLxT) 5cm x 15mm x (0.3~0.399)mm	Assay: 90.0%-110.0% of the labeled amount Total Aerobic Microbial Count: NMT 10^2 cfu/g Total Yeast and Mold Count: NMT 10^1 cfu/g Staphylococcus aureus: Absent Pseudomonas aeruginosa: Absent	The specifications are identical between the subject and the reference device.
Indications for Use	Curajel™ Oral Gel is intended for use as an oral wound dressing to protect ulcer tissue by forming a physical barrier on the wound tissue to avoid further irritation and thus to relieve pain. It is indication for use with all types of ulcers and small wounds of the oral mucosa including canker sores, aphthous ulcers, and injuries such as traumatic ulcers caused by self-biting, braces and ill-fitting dentures.	OraCure® is intended for use as an oral wound dressing to protect ulcer tissue by forming a physical barrier on the wound tissue to avoid further irritation and thus to relieve pain. It is indicated for use with all types of ulcers and small wounds of the oral mucosa including canker sores, aphthous ulcers, and injuries such as traumatic ulcers caused by self-biting, braces, and ill-fitting dentures.	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 between the subject and the predicate device which is cleared for OTC use. The indications are similar between the subject and the reference device.
Applications/ Day	Apply to mucosal wounds 2-3 times daily	Single Use Sheet	Apply to mucosal wounds 2-3 times daily	Similar between the subject and the predicate device.

Characteristic	Subject Device (Present Submission)	Predicate Device	Reference Device	Comparison
				Identical between the subject and the reference device.
Area of Use	Oral mucosa	Oral mucosa	Oral mucosa	Identical
Product Form	Gel	Gel-type patch/sheet	Gel	The subject device is similar to the predicate device as both devices use a gel-type application. The subject device is identical to the reference device.
Sterility	Non-sterile	Non-sterile	Non-sterile	Identical
Patient Population	Adults & Pediatrics	Not specified in 510(k) summary or publicly available information	Adults & Pediatrics	Identical between the subject and the reference device.
Prescription Use	Over the Counter	Over the Counter	Prescription Use	Identical between the subject and the predicate device. There are several other similar products in the OLR product code that are also cleared for OTC use and are listed in the summary below.

The subject and predicate devices are identical in intended use, indications for use and over the counter use. As stated above and discussed in the table, the subject device is a similar technology to the predicate as both are oral wound dressings that provide a gel-type protective barrier at the site of application to prevent irritation and relieve pain from mouth wounds. The minor differences in technology between the gel form of the subject device and the gel-type sheet of the predicate device can be explained by the reference device which is identical in formulation and mechanism of action to the subject device. The technological differences do not, raise different questions of safety or effectiveness.

Performance Testing

As stated above, the technological characteristics of Curajel™ Oral Gel are similar to those of the

predicate device and identical to those of the reference device, Silatrix Oral Gel, cleared in K252425.

Comprehensive biocompatibility, stability/shelf life, and antimicrobial preservative efficacy testing was conducted in support of the prior Rx clearance of the device under K252425 to confirm product conformance with device requirements and demonstrate that Curajel™ Oral Gel is as safe, as effective, and substantially equivalent to its legally marketed predicate device. For completeness, the same testing is described again here and included throughout this submission.

Biocompatibility Testing

Like the predicate device, Curajel™ Oral Gel has conducted adequate biocompatibility testing in accordance with ISO 10993 and FDA guidance.

The same biocompatibility testing is being submitted from the Rx version of the device cleared under K252425. Testing was conducted on the final, finished device and 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.

Shelf Life and Antimicrobial Preservative Efficacy Testing

Like the predicate device, Curajel™ Oral Gel has conducted adequate microbial limit testing and shelf-life testing to address FDA requirements.

As the subject device is the exact same device cleared in K252425, shelf life and stability testing was not repeated. The same shelf life and stability testing is being submitted from the reference device K252425.

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.

Human Factors Analysis

A human factors analysis was conducted for Curajel™ Oral Gel, including identification of the intended users, use environments, critical tasks, and potential use-related hazards. Curajel™ Oral Gel is an OTC product with low complexity, minimal risk of serious harm, and established user interfaces consistent with comparator legally marketed products. There are no critical tasks that would require a human factors validation study. All risks were addressed through user-centered labeling and risk analysis. This is consistent with other oral wound dressings legally marketed for OTC use under product code OLR including the predicate device OraCure (K183436).

Conclusions

The biocompatibility, stability/shelf life, and USP antimicrobial preservative efficacy studies demonstrated the subject device is biocompatible; maintains product specifications and stability over the labeled shelf life; and has substantially equivalent performance to the predicate and reference devices with respect to meeting the specifications established for its intended use.

The human factors analysis demonstrated that the subject device can be used safely and effectively by the intended OTC user population and is substantially equivalent to the predicate device with respect to the indications for use and labeling.

These results demonstrate that Curajel™ Oral Gel is as safe, as effective, and is substantially equivalent to the legally marketed predicate device.