February 10, 2026

OviGenex LLC
Thomas Hyland
CEO
2630 Homestead Place
Dominguez Hills, California 90220

Re: K253140
Trade/Device Name: CollOvine™ Wound Powder
Regulatory Class: Unclassified
Product Code: KGN
Dated: December 30, 2025
Received: December 30, 2025

Dear Thomas Hyland:

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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
OHT4: Office of Surgical and
Infection Control 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.

Submission Number *(if known)*

K253140

Device Name

CollOvine™ Wound Powder

Indications for Use *(Describe)*

CollOvine™ Wound Powder is indicated for the management of wounds including:
- full-thickness & partial-thickness wounds
• pressure ulcers
• venous ulcers
• diabetic ulcers
• partial thickness burns
• donor sites and other surface wounds
• abrasions
• traumatic wounds healing by secondary intention
• acute wounds

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1. DATE PREPARED

5th September 2025

2. SUBMITTER

OviGenex LLC
2630 Homestead Place
Rancho Dominguez,
California 90220

3. CONTACT PERSON

Thomas Hyland
CEO
Cell (+44) 7984432366
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4. DEVICE NAME

Classification Name:	Wound dressing with animal derived materials
Common/Usual Name:	Wound dressing
Proprietary Name:	CollOvine™ Wound Powder

5. DEVICE CLASSIFICATION

Product Code/Classification Number:	KGN
Regulatory Class:	Unclassified
Primary Predicate device	K030774 – Stimulen™

6. INDICATIONS FOR USE

CollOvine™ Wound Powder is designed for use with adults only, and for the management of exuding wounds including:

- full-thickness & partial-thickness wounds
- pressure ulcers
- venous ulcers
- diabetic ulcers
- partial thickness burns
- donor sites and other surface wounds
- abrasions
- traumatic wounds healing by secondary intention
- acute wounds

- *Precautions:*

CollOvine™ Wound Powder should only be used under the direct supervision of a wound care professional. When visible signs of infection are present then CollOvine™ Wound Powder should not be used and an appropriate course of treatment for infections should be followed. Stop using immediately if an allergic reaction is suspected

- *Contraindications:*

CollOvine™ Wound Powder are not indicated for deep second-degree, or third-degree burns, wounds with active vasculitis, pregnant or breast-feeding women, or children, or for patients with known sensitivity to collagen or lanolin.

CollOvine™ Wound Powder indications for use are the same as the primary predicate Stimulen™ collagen wound powder.

Indications for Use	
CollOvine wound powder K253140	Stimulen™ K030774
• full-thickness & partial-thickness wounds	• full-thickness & partial-thickness wounds
• pressure ulcers	• pressure ulcers
• diabetic ulcers	• diabetic ulcers
• venous ulcers	• venous ulcers
• donor sites and other surface wounds	• donor sites and other surface wounds
• abrasions	• abrasions
• traumatic wounds healing by secondary intention	• traumatic wounds healing by secondary intention
• partial thickness burns	• partial thickness burns
• acute wounds	• acute wounds

7. DEVICE DESCRIPTION

CollOvine™ Wound Powder is a sterile advanced wound care device composed of medical grade ovine collagen. CollOvine Wound Dressing is soft, absorbent, and readily conforms to the wound bed.

CollOvine™ Wound Powder is intended to maintain the moist wound environment.

CollOvine™ Wound Powder is a primary wound dressing that can be sprinkled over the wound bed without the need to precut.

CollOvine™ Wound Powder should be used with suitable non-occlusive absorbent secondary dressing and secured with standard non-irritating fixations such as medical grade tape or semi-occlusive dressing as appropriate.

CollOvine™ Wound Powder is a primary dressing, to maintain the moist wound bed environment.

CollOvine™ Wound Powder is soft, pliable and free flowing.

The ovine collagen for CollOvine™ Wound Powder is obtained from animal tissue, with sourcing, collection, storage and viral inactivation carried out in compliance with ISO22442.

8. TECHNOLOGICAL COMPARISON

Attribute	CollOvine Powder	Stimulen (Primary Predicate)
510(k) Number	K253140	K030774
Classification	Wound Dressing with animal derived material	Wound Dressing with animal derived material
Product Code	KGN	KGN
Regulatory Class	Unclassified	Unclassified
Indications for use	CollOvine Wound powder is indicated for the management of exuding wounds including: Full-thickness & partial-thickness wounds; pressure ulcers; venous ulcers; diabetic ulcers; donor sites and other surface wounds; abrasions; traumatic wounds healing by secondary intention	Stimulen™ is indicated for the management of exuding wounds including: Full thickness & partial thickness wounds; pressure ulcers; venous ulcers; diabetic ulcers; partial thickness burns; donor sites and other surface wounds; abrasions; traumatic wounds healing by secondary intention; acute wounds
Manufacturer	OviGenex LLC.	Southwest technologies Inc
Material	Collagen	Collagen
Origin	Ovine hide	Bovine hide
Device Characteristics	Collagen	Soluble, modified collagen.
Biocompatible	Yes, ISO 10993-1	Yes, ISO 10993-1
Reusable	Single Use Device	Single Use Device
Sterilization Method	Gamma irradiation	Gamma Irradiation

9. NON-CLINICAL / CLINICAL SUMMARY and CONCLUSIONS

CollOvine Wound dressing was tested for biocompatibility in compliance with ISO 10993 Part 1 B

The following safety testing was conducted in accordance with ISO 10993 Part 1 Biological Evaluation of Medical Devices to support the biocompatibility of this product.

- Acute systemic toxicity (in mice)
- Primary skin irritation (in rabbits)
- Dermal sensitization (in Guinea pigs)
- Pyrogenicity (in rabbits)
- Subacute Systemic toxicity (in rats; 30 days intraperitoneal route)
- Subcutaneous implant (in rats, 1-week and 4-weeks)
- In vitro Cytotoxicity (Direct cell contact)
- Chemical Characterization
- Toxicological Risk assessment

pH and absorbency of CollOvine wound powder was tested and found to be similar to that of the primary predicate Stimulen wound powder.

CollOvine is tested for Endotoxins in accordance with USP85, using the Limulus Amoebocyte Lysate (LAL) method.

In conclusion, CollOvine wound powder is substantially equivalent to the predicate device.