August 27, 2026

Berkeley Advanced Biomaterials
Bradley Glover
COO
2800 Seventh St.
Berkeley, California 94710

Re: K260711
Trade/Device Name: Accelagen Plus Surgical Matrix, 1cc (CG-01AP);Accelagen Plus Surgical Matrix, 3cc (CG-03AP);Accelagen Plus Surgical Matrix, 5cc (CG-05AP);Accelagen Plus Surgical Strip, 125x25x2mm (CG-125X25AP);Accelagen Plus Surgical Strip, 250x25x2mm (CG-250X25AP)
Regulatory Class: Unclassified
Product Code: KGN
Dated: April 15, 2026
Received: April 15, 2026

Dear Bradley Glover:

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,

MUSTAFA A. MAZHER -S

For 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.

510(k) Number *(if known)*
K260711

Device Name
Accelagen Plus Surgical Matrix

Indications for Use *(Describe)*
Accelagen Plus Surgical Matrix is indicated for the management of wounds including:
• Partial and full-thickness wounds
• Pressure ulcers (stage I-IV)
• Venous ulcers
• Diabetic ulcers
• Chronic vascular ulcers
• Ulcers caused by mixed vascular etiologies
• Tunneled/undermined wounds
• Surgical wounds (e.g., incisions, donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)
• Trauma wounds (e.g., abrasions, lacerations, partial thickness burns and skin tears)
• Draining wounds
• First-degree burns and superficial second-degree burns.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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."

Accelagen™ Plus Surgical Matrix
510(k) Summary – K260711

I. Contact Details

Applicant Name:	Berkeley Advanced Biomaterials
Applicant Address:	2800 Seventh St Berkeley CA, 94710
Applicant Contact:	Bradley Glover, Ph.D. 510-883-0500
Date Prepared:	August 27, 2026

II. Device Name

Trade Name:	Accelagen™ Plus Surgical Matrix
Common Name:	Collagen Wound Matrix
Regulation Name:	Wound Dressing with Animal-Derived Material(s)
Product Code:	KGN

III. Predicate/Reference Devices:

Predicate Device:	NovoGen Wound Matrix (K220498)
Reference Device:	CoMatryx Collagen Wound Dressing (K171645)

IV. Intended Use / Indications for Use

Accelagen™ Plus Surgical Matrix is indicated for the management of wounds including:

- Partial and full-thickness wounds
- Pressure ulcers (stage I-IV)
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcers
- Ulcers caused by mixed vascular etiologies
- Tunneled/undermined wounds
- Surgical wounds (e.g., incisions, donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)
- Trauma wounds (e.g., abrasions, lacerations, partial thickness burns and skin tears)
- Draining wounds
- First-degree burns and superficial second-degree burns.

The subject device has the same general intended use as the predicate – to manage wounds.

V. Device Description

Accelagen™ Plus Surgical Matrix (Accelagen™ Plus) is 100% resorbable and is composed of bovine type I/III collagen, 45S5 bioactive glass, and sodium hyaluronate.

The product is supplied sterile and is available in two forms: a Powder and a Strip. Accelagen™ Plus acts as a scaffold for cellular migration and tissue growth. The device will absorb fluid (wound exudate, blood, sterile saline, sterile water) and form a soft, pliable material that maintains a moist wound environment to support natural wound healing.

VI. Technological Comparison

The subject and predicate devices are based on the following substantially equivalent technological and functional elements:

- Composition – Both are comprised of bovine-derived collagen, 45S5 bioactive glass, and either sodium hyaluronate or citric acid to support structural integrity and the provision of a moist environment.
- Mode of application – Topical.
- Degradation profile – Both are resorbable.

The minor technological differences between the devices raise no different questions of safety or effectiveness, as both products have similar type and duration of contact with the body, similar materials, and serve the same primary function. Performance data, including bench and animal testing, demonstrates that the subject device is substantially equivalent to the predicate device.

A summary table comparing the subject device to the predicate devices is shown below.

VII. Performance Data

Product performance was established through a variety of tests on the bench and in a porcine model, as summarized below.

Biocompatibility per ISO 10993: The final device was evaluated for the following endpoints: cytotoxicity, sensitization, irritation, acute systemic toxicity, genotoxicity, material-mediated pyrogenicity, implantation, subacute/subchronic toxicity, carcinogenicity, and chronic toxicity.

Product characterization testing:

- Visual assessment of product; microstructure analysis via scanning electron microscopy (SEM)
- Weight, bulk volume, and density
- Surface area
- Hydration and handling
- Hydrated pH characterization
- Collagen solubility
- Bioglass characterization – Bioglass particle distribution, x-ray fluorescence (XRF), and x-ray diffraction (XRD).

Sterilization:

A gamma sterilization validation was conducted according to ISO 11137-2 to support a sterility assurance level of 10^{-6}.

Animal Testing:

Accelagen Plus™ was evaluated in a 28-day porcine, full thickness wound study and compared against the CoMatryx reference device. Multiple full-thickness wounds were created on the back of each animal and the test articles were applied. Dressing changes and test article re-application were conducted at multiple timepoints throughout the study. At each dressing change, wounds were assessed by morphometric wound area measurements and a Bates-Jensen wound assessment. Additionally, at 7 and 28 days, wounds were harvested and assessed via histology and semi-quantitative histopathology scoring for inflammation, granulation tissue, and epithelialization.

All testing showed that the product performed as expected and met prespecified acceptance criteria.

VIII. Conclusion

Accelagen™ Plus has the same intended use and similar indications for use, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the device's fundamental clinical purpose, nor affect its safety or effectiveness when used as labeled. In addition, the minor technological differences between the subject and predicate devices raise no different questions of safety or effectiveness, and they are further supported by performance data and the clearance of the reference device with comparable technological characteristics.

Characteristic	Accelagen™ Plus Surgical Matrix	CoMatryx (Strukmyer)	NovoGen Wound Matrix (Novabone Products, LLC)
510(k) Number	K260711	K171645	K220498
Product Code	KGN	KGN	KGN
Intended Use / Indications for Use	Accelagen™ Plus Surgical Matrix is indicated for the management of wounds including: • Partial and full-thickness wounds • Pressure ulcers (stage I-IV) • Venous ulcers • Diabetic ulcers • Chronic vascular ulcers • Ulcers caused by mixed vascular etiologies • Tunneled/undermined wounds • Surgical wounds (e.g., incisions, donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence) • Trauma wounds (e.g., abrasions, lacerations, partial thickness burns and skin tears) • Draining wounds • First-degree burns and superficial second-degree burns	CoMatryx Collagen Wound Dressing may be used in the management of partial and full thickness wounds, pressure (stage I-IV) and venous ulcers, ulcers caused by mixed vascular etiologies, venous stasis and diabetic ulcers, 1st and 2nd degree burns, cuts, abrasions, and surgical wounds.	NovoGen Wound Matrix is indicated for the management of wounds including: • Partial and full-thickness wounds • Pressure ulcers • Venous ulcers • Diabetic ulcers • Chronic vascular ulcers • Tunneled / undermined wounds • Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser, surgery, podiatric, wound dehiscence) • Trauma wounds (abrasions, lacerations, partial thickness burns, and skin tears) • Draining wounds
Composition	Type I/III Bovine Collagen, 45S5 Bioactive Glass, Sodium Hyaluronate	Type I/III Bovine Collagen	Type I Bovine Collagen, 45S5 Bioactive Glass, Citric Acid
Sterile	Yes	Yes	Yes
Rx / OTC	Rx	Rx	Rx
Absorbable	Yes	Yes	Yes
Product Form	Particulate (Powder) and Strip/Sheet	Particulate (Powder)	Sheet
Reapplication	As needed	As needed	As needed