February 19, 2026

Lacerta Life Sciences
% Justin Gracyalny
Senior Manager, Regulatory and Technical Compliance
Secure BioMed Evaluations
7828 Hickory Flat Hwy Suite 120
Woodstock, Georgia 30188

Re: K260218
Trade/Device Name: LacertaMatrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: January 23, 2026
Received: January 23, 2026

Dear Justin Gracyalny:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

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.*

510(k) Number *(if known)*
K260218

Device Name
LacertaMatrix

Indications for Use *(Describe)*
LacertaMatrix is indicated for use in the management of the following wounds:
• 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

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."*

**510(k) SUMMARY:**
Lacerta Life Sciences LacertaMatrix

| | |
|---|---|
| **Date Prepared** | February 17, 2026 |
| **Sponsor** | Lacerta Life Sciences<br>7842 Hickory Flat Hwy<br>Woodstock, GA 30188 |
| **510(k) Contact** | Secure BioMed Evaluations<br>Justin Gracyalny, MSE, RAC<br>7828 Hickory Flat Highway, Suite 120<br>Woodstock, GA 30188<br>770-837-2681 (direct)<br>Regulatory@SecureBME.com (email) |
| **Trade Name** | LacertaMatrix |
| **Common Name** | Wound Dressing |
| **Code – Classification** | KGN Wound Dressing with Animal-Derived Material(s) |
| **Predicate Device** | K252673 Lacerta Life Sciences LacertaMatrix |
| **Device Description** | LacertaMatrix is a single use, non-pyrogenic wound dressing intended for use in local management of full thickness and partial thickness wounds.<br><br>LacertaMatrix includes alligator derived hyaluronic acid (HA) and is provided sterile in various size offerings up to 100cm$^2$ in a dual pouch configuration for aseptic transfer. Following placement, LacertaMatrix is gradually broken down and resorbed over time (typically over a period of within 2 weeks), as new tissue forms in its place. |
| **Indications for Use Statement** | LacertaMatrix is indicated for use in the management of the following wounds:<br>• partial and full-thickness wounds<br>• pressure ulcers<br>• venous ulcers<br>• diabetic ulcers<br>• chronic vascular ulcers<br>• tunneled / undermined wounds<br>• surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)<br>• trauma wounds (abrasions, lacerations, partial thickness burns, and skin tears)<br>• draining wounds |

**Comparison of Technological Characteristics**

| Characteristic | Subject Device<br>Lacerta Life Sciences<br>LacertaMatrix | Predicate Device<br>Lacerta Life Sciences<br>LacertaMatrix (K252673) |
|---|---|---|
| Intended Use | Management of wounds | Management of wounds |
| Primary Function | Provide a moist wound healing environment.<br>Provide a scaffold that allows for wound healing. | Provide a moist wound healing environment.<br>Provide a scaffold that allows for wound healing. |
| Device Form | Matrix Sheet | Matrix Sheet |
| Composition | Porcine Gelatin / Hyaluronic Acid | Porcine Gelatin / Hyaluronic Acid |
| Animal Origin | Alligator (HA) /<br>Porcine (Gelatin) | Alligator (HA) /<br>Porcine (Gelatin) |
| Sizes | Sizes ranging from 1 – 100cm$^2$ | Sizes ranging from 6.25 – 100cm$^2$ |
| Packaging | Dual sterile barrier in shelf-carton or mailer | Dual sterile barrier in shelf-carton |
| Non-Pyrogenic | Yes | Yes |
| Sterilization | E-beam,<br>SAL $10^{-6}$ | E-beam,<br>SAL $10^{-6}$ |
| Endotoxin | <20 EU/device | <20 EU/device |
| Prescription Only | Yes | Yes |

**Technological Characteristics**

There are no significant technological differences between the subject and predicate device. The subject device uses identical materials, is of a similar size, has identical design properties, and has the same intended use as the predicate device.

The purpose of this submission was to make minor modifications to the device labeling / instructions for use, expand the lower range of available size offerings, and add an additional packaging configuration. All new size offerings are within the range of the cleared reference device (K213607). Differences in the device labeling are addressed via supporting clinical data. Rationales were provided to support applicability of previous sterilization and distribution validations. All data supports that any technological differences will not raise new questions of safety or effectiveness.

**Performance Testing Summary**

The following testing was performed to support substantial equivalence:

- Human Repeat Insult Patch Testing (HRIPT) Testing and Skin Prick Testing
- Sterilization Validation Adoption Rationale

- Distribution Validation Adoption Rationale

No visible skin reactions were noted at any evaluation timepoint for the HRIPT testing conducted.

**Conclusions**

Based on the similarities of the intended use/indications for use, technological and functional characteristic, and the results of the performance testing, the subject device is substantially equivalent to the legally marketed predicate device.