December 22, 2025

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

Re: K252673
Trade/Device Name: LacertaMatrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: November 25, 2025
Received: November 25, 2025

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 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.

510(k) Number *(if known)*
K252673

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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	December 22, 2025
Sponsor	Lacerta Life Sciences 7842 Hickory Flat Hwy Woodstock, GA 30188
510(k) Contact	Secure BioMed Evaluations Justin Gracyalny, MSE, RAC 7828 Hickory Flat Highway, Suite 120 Woodstock, GA 30188 770-837-2681 (direct) Regulatory@SecureBME.com (email)
Trade Name	LacertaMatrix
Common Name	Wound Dressing
Code – Classification	KGN Wound Dressing With Animal-Derived Material(s)
Predicate Device	K200413 Aroa Biosurgery Ltd. Symphony
Device Description	LacertaMatrix is a single use, non-pyrogenic wound dressing intended for use in local management of full thickness and partial thickness wounds. LacertaMatrix includes alligator derived hyaluronic acid (HA). LacertaMatrix 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. This device is limited to only one-time application to the wound. This device can only be used once within 24 hours and should be completely remove by rinsing with PBS to remove any residual device. Second application is restricted. Please use other FDA cleared dressing.
Indications for Use Statement	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

Comparison of Technological Characteristics

Characteristic	Subject Device Lacerta Life LacertaMatrix	Primary Predicate Aroa Biosurgery Ltd. Symphony (K200413)
Intended Use	Management of wounds	Management of wounds
Primary Function	Provide a moist wound healing environment. Provide a scaffold that allows for wound healing.	Provide a moist wound healing environment. Provide a scaffold that allows for wound healing.
Device Form	Matrix Sheet	Matrix Sheet
Composition	Porcine Gelatin / Hyaluronic Acid	Ovine Collagen / Bacterial Derived Hyaluronic Acid
Animal Origin	Alligator (HA) / Porcine (Gelatin)	Ovine
Sizes	Sizes ranging from 6.25 – 100cm^2	Sizes ranging from 1 – 400cm^2
Non-Pyrogenic	Yes	Unknown
Sterilization	E-beam, SAL 10^{-6}	Ethylene Oxide, 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 devices. The subject device uses similar materials, is of a similar size, has similar design properties, and has the same intended use as the predicate devices. Differences such as the animal derived material source, device formulation, and sterilization method are addressed via supporting biocompatibility testing, sterilization validations, non-clinical performance testing, and supporting clinical data. All data supports that any technological differences will not raise new questions of safety or effectiveness.

Performance Testing Summary

The following non-clinical testing was performed to support substantial equivalence:

- Viral Inactivation per ISO 22442-3
- Sterilization Validation Per ISO 11137-1, ISO 11137-2
- Bacterial Endotoxin per USP <85>, ANSI/AAMI ST72
- Matrix Microstructure Characterization Testing
- Hyaluronic Acid Characterization Testing

All testing met the predetermined acceptance criteria (where applicable) and supports substantial equivalence to the predicate devices.

LacertaMatrix was found to be biocompatible for its intended use when tested in compliance with ISO 10993-1. The following endpoints were addressed via testing in accordance with ISO 10993-1 and applicable FDA guidance:

- Cytotoxicity per ISO 10993-5
- Sensitization per ISO 10993-10
- Irritation per ISO 10993-23
- Acute systemic toxicity per ISO 10993-11
- Material mediated pyrogenicity per ISO 10993-11, USP <151>
- Implantation per ISO 10993-6
- Subacute systemic toxicity, chronic toxicity, genotoxicity, and carcinogenicity endpoints were addressed via chemical characterization per ISO 10993-18 and supporting toxicological risk assessment per ISO 10993-17

A full thickness porcine wound healing study found equivalent wound healing performance for the LacertaMatrix when compared to the additional predicate device and untreated control sites.

Clinical testing was performed to support the safety of the alligator HA animal source and included a human repeat insult patch test (HRIPT) and skin prick test. In the HRIPT test, no visible skin reactions were noted at any evaluation timepoint. In the skin prick test, no difference was noted between the subject device and negative control. All clinical testing supports that any minor differences in animal derived source material do not impact substantial equivalence.

Conclusions

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