



June 18, 2026

Ecm Therapeutics, Inc.
Cynthia Berringer
Vice President, Regulatory Affairs
118 Marshall Dr.
Warrendale, Pennsylvania 15086

Re: K253521
Trade/Device Name: Ecmt-100 Wmd
Regulatory Class: Unclassified
Product Code: KGN
Dated: May 21, 2026
Received: May 21, 2026

Dear Cynthia Berringer:

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 Infection Control
and 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

Indications for Use

510(k) Number (if known)

K253521

Device Name

ECMT-100 WMD

Indications for Use (Describe)

ECMT-100 WMD is intended 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-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, partial thickness burns, skin tears), draining wounds. The device is intended for single-use.

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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K253521

1. SUBMITTER INFORMATION

Applicant: ECM Therapeutics, Inc.
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Address 118 Mashall Drive
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CONTACT INFORMATION

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2. DEVICE INFORMATION

Device Name: ECMT-100 WMD
Common Name: Animal-Derived, Extracellular Matrix Wound Product
Regulation Number: N/A
Regulation Name: Wound Dressing With Animal-Derived Material(s)
Product Code: KGN
Regulatory Class: Unclassified

3. PREDICATE DEVICE INFORMATION

Device Name: MicroMatrix® Flex
510(k) Number: K230980
Manufacturer: ACell, Inc. (subsidiary of Integra LifeSciences Corp.)

The predicate device has not been subject to a design related recall.

4. DEVICE DESCRIPTION

The ECMT-100 WMD is a colloidal hydrogel device for the management of wounds. The device is delivered to the wound site from a syringe. ECMT-100 WMD is composed of extracellular matrix derived from decellularized porcine dermis. The device contained inside of the 3mL syringe is packaged in a carton inside of a sealed foil pouch and terminally sterilized using electron beam irradiation.

5. INDICATIONS FOR USE

ECMT-100 WMD is intended 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-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, partial thickness burns, skin tears), draining wounds. The device is intended for single-use. The device is intended for use in patients aged 18 years and older.

6. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

ECMT-100 WMD has identical intended use and indications for use as the cleared predicate MicroMatrix® Flex (K230980) device.

The technological characteristics of ECMT-100 WMD are substantially equivalent to the predicate device. Both devices are intended for single-use only and are resorbable. Both devices originate from porcine animal tissue-derived collagen extracellular matrix (ECM) and are considered flowable devices. The following table provides an overview of the comparison between the subject and predicate device.

Table 01: Comparator Table for Subject and Predicate Devices

	ECMT-100 WMD Subject Device	MicroMatrix® Flex Predicate Device (K230980)
510(k) No.	TBD	K230980
Device Class	Unclassified	Unclassified

Product Code	KGN	KGN
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	ECMT-100 WMD Subject Device	MicroMatrix® Flex Predicate Device (K230980)
Regulation Number	N/A	N/A
Classification Name	Wound Dressing With Animal-Derived Material(S)	Wound Dressing With Animal-Derived Material(S)
Patient Population	Adult Patients	Adult Patients
Indications for Use	ECMT-100 WMD 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-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, partial thickness burns, skin tears), draining wounds. The device is intended for one time use.	MicroMatrix Flex 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-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, partial thickness burns, skin tears), draining wounds. The device is intended for one time use.
Material Source	Porcine Dermis	Porcine Urinary Bladder Matrix (UBM)
Material Type	Collagen, Extracellular Matrix	Collagen, Extracellular Matrix
Crosslinked Collagen	No	No
Decellularized	Yes	Yes
Resorbable	Yes	Yes
Configuration as Packaged	Gel	Particulate
Technological Features	Device is in a ready-to-use gel consistency, provided in a sterile syringe with a luer-locking syringe cap.	Device is hydrated to a paste consistency using saline in a dual syringe-to-syringe connector and then dispensed through an optional tip.
Reusable	Single Use Device	Single Use Device
Biocompatible	Yes	Yes
Packaging	Single use syringe contained in a carton box. The carton box is contained within a sealed foil pouch.	Preformed rigid tray with die-cut lid

	ECMT-100 WMD Subject Device	MicroMatrix® Flex Predicate Device (K230980)
Sterilization	E-Beam	E-Beam
Storage	Store in a clean, refrigerated environment at temperatures between 2° and 8°C (36° and 46°F) in an unopened and undamaged package. Protect from freezing, excessive heat, and high humidity.	Store in a clean, dry environment at room temperature in an unopened and undamaged package. Protect from freezing, excessive heat, and high humidity.

7. PERFORMANCE DATA

7.1. Biocompatibility Testing

Biocompatibility was tested in compliance with ISO 10993-1 and the following end points were tested: cytotoxicity, sensitization, intracutaneous reactivity, material mediated pyrogenicity, systemic toxicity testing, genotoxicity, implantation testing, chemical characterization, and biological and toxicological risk assessments were completed.

7.2. Performance Testing

The following laboratory testing was conducted to demonstrate that the ECMT-100 WMD meets its design requirements and performs as intended. The tests include:

- Viral Inactivation / Viral Safety
- Endotoxin
- Rheology / pH / Injectability Force
- Product Stability
- Packaging Stability
- Sterilization Validation
- Biochemical Characterization
- Simulated Use Study

8. CONCLUSION

The results of the biocompatibility and performance testing described above demonstrate that the ECMT-100 WMD is as safe and effective as the predicate device and supports a determination of substantial equivalence.