December 15, 2025

Machina Medical Inc.
Tiffini Wittwer
Executive Vice President Compliance and Regulatory Affairs
3055 Bellingrath Blvd.
Roswell, Georgia 30076

Re: K250319
Trade/Device Name: MFUSE™
Regulatory Class: Unclassified
Product Code: QSY
Dated: November 19, 2025
Received: November 21, 2025

Dear Tiffini Wittwer:

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)*
K250319

Device Name
MFUSE™

Indications for Use *(Describe)*
MFUSE™ is indicated for temporary external use for controlling moderate to severe bleeding.

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

[AS REQUIRED BY 21 CFR 807.92]

Submitter Information

Sponsor and Application Correspondent:	Tifini Wittwer Executive Vice President Compliance & Regulatory Affairs 3055 Bellingrath Blvd Roswell GA 30076
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Contact person:	Tiffini Wittwer
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Date Prepared:	December 12, 2025
Device Identification:	MFUSE™
Common Name:	Hemostatic would dressing without thrombin or other biologics
Device Class:	Unclassified
Review Panel:	General & Plastic Surgery
Product Code:	QSY
Regulation Number:	Not Applicable
Predicate Devices:	Primary TRAUMAGEL® (K240713)

Device Description

MFUSE™ is a sterile, single-use, disposable device designed to stop bleeding by creating an barrier over the wound. The device will be used by healthcare professionals to temporarily stop moderate to severe bleeding. The device is comprised of polyacrylic acid (PAA) in a chitosan matrix. The PAA / chitosan structure is mixed with mineral oil to form a paste that is cream to light yellow in color. MFUSE™ is provided in a 5gm (mL) quantity syringe. The syringe is packaged in a foil pouch and is terminally sterilized with gamma sterilization.

Indications for Use

MFUSE™ is indicated for temporary external use for controlling moderate to severe bleeding.

Substantial Equivalence

The subject device, MFUSE™, is substantially equivalent to the predicate device TRUAMAGEL® cleared under K240713. The intended use, indications for use are the same as the predicate.

MFUSE™ and the predicate are technologically similar in mechanisms of action and sterilization. MFUSE™ and the predicate device form a mechanical barrier that stops the flow of bleeding and allows the body to create a natural clot. The subject device and the predicats contain non-animal derived material(s) that physically adhere with tissue surface, and can be removed with normal saline.

MFUSE™ and TraumaGel® both use chitosan and both are packaged in a syringe.

MFUSE™ is technologically different than the predicate in the material. MFUSE™ uses PAA. TraumaGel® uses sodium alginate. Performance bench testing, GLP animal study, and biocompatibility testing demonstrate that the difference in materials does not introduce any new questions of safety and effectiveness relative to the predicate device.

Substantial Equivalence

Parameters	**Subject Device**	**Predicate Device**	**Comments**
Name	MFUSE™	TRAUMAGEL®	N/A
510(k) Number	K250319	K240713	N/A
Manufacturer	Machina Medical Inc.	Cresilon Inc.	N/A
Product Code	QSY	QSY	Same
Device Class	Unclassified	Unclassified	Same
Intended/ Indications for use	MFUSE™ is indicated for temporary external use for control of moderate to severe bleeding.	TRAUMAGEL® is a hemostatic gel indicated for temporary external use for controlling moderate to severe bleeding.	Same
Rx/OTC	Rx	Rx	Same
Single Use	Yes	Yes	Same
Form Factor	Hydrogel	Hydrogel	Same
Materials	Polyacrylic acid (PAA), plant derived chitosan [poly (N-acetyl-D-glucosamine, D-glucosamine)], mineral oil (replaced by water)	Chitosan [poly (N-acetyl-D-glucosamine, D-glucosamine)] and sodium alginate	Biocompatibility testing, GLP Animal testing, and Material Characterization with Toxicological Risk Assessment demonstrate that design differences do not alter the established safety and effectiveness when compared to the predicate.
Mechanism of Action	When directly applied to the source of bleeding, the oil in MFUSE™ is displaced by water exuding from injured tissue. The water is absorbed by the PAA / Chitosan matrix and rapidly adheres to the wound site. The formed hydrogel creates a mechanical barrier that stops the flow of bleeding and	When directly applied to a source of bleeding, the TRAUMAGEL® hemostatic gel rapidly adheres to the wound site. The hemostatic gel forms a mechanical barrier that stops the flow of bleeding and allows the body to create a natural clot.	Similar mechanisms of action and adherence to skin. Performance testing and GLP animal testing demonstrate specific adherence and material transformation differences to not alter the established safety and effectiveness when compared to the predicate.

Parameters	Subject Device	Predicate Device	Comments
	allows the body to create a natural clot.		
Removal	Soak with normal saline or sodium bicarbonate	Soak with normal saline	Same
Packaging	Syringe	Syringe	Same
Sterilization	Terminally sterilize with gamma irradiation SAL of 10^{-6}	Terminally sterilized with gamma irradiation SAL of 10^{-6}.	Same

Non-clinical Testing:

The subject device has been evaluated through a series of nonclinical studies to demonstrate that the device meets acceptance criteria for its intended use.

1. Biocompatibility Testing

Biocompatibility tests have been performed per the requirements of ISO 10993-1:2018 as a surface device used on breached or compromised surface with limited duration contact (<24 hours). MFUSE™ complies with all tests and standards as identified below

Test Name	Purpose	Results
Cytotoxicity testing ISO 10993-5	To verify cytotoxicity potential of the device	Passed
Sensitization ISO 10993-10	To verify the sensitization potential of the device	Passed
Irritation ISO 10993-23	To verify the irritation potential of the device	Passed
Acute Systemic toxicity ISO 10993-11	To evaluate the potential for medical device material to cause adverse systemic reaction	Passed
Material Mediated Pyrogenicity ISO 10993-11	To verify the pyrogenicity potential of the device	Passed
Material Characterization ISO 10993-18	To identify and quantify the chemical constituents of a medical device to support toxicological risk assessment	Passed
Toxicological Risk Assessment ISO 10993-17	To determine safe exposure levels and evaluate the toxicological risk of chemical constituents from medical devices.	Passed

Test Name	Purpose	Results
Bacterial Endotoxins ANSI/AAMI ST72:2019	To verify the endotoxin levels do not exceed 20EU per application	Pass

2. Performance Bench Testing

As part of design verification testing, representative samples of the device underwent absorption, T-peel, tensile, lap shear testing, and other tests as applicable to the subject device. Results demonstrate that all device performance specifications are met.

3. Non-Clinical Animal Studies

In vivo GLP animal performance testing was conducted in a porcine carotid arteriotomy model to evaluate MFUSE™ and an FDA cleared device (K061079). Both the subject device and FDA cleared device (K061079) performed as intended. This testing demonstrated substantially equivalent performance between the devices.

4. Sterilization

MFUSE™ is terminally sterilized using gamma irradiation to a Sterility Assurance Level of 10^{-6}.

Conclusion:

The indications for use, sterilization, mechanism of action, and removal are the same as the predicate. The packaging, form factor, and use of chitosan are similar to TraumaGel® the predicate. Performance bench testing, GLP animal study, and biocompatibility testing demonstrate that the difference in materials does not introduce any new questions of safety and effectiveness relative to the predicate devices.