April 7, 2026

InnovaCorium, Inc.
Marcelo Buzzi
CEO
Uf Innovate
747 SW 2nd Ave., Suite 354
Gainesville, Florida 32601

Re: K254191
Trade/Device Name: IWD-Gel™
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 27, 2026
Received: February 27, 2026

Dear Marcelo Buzzi:

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
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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)*
K254191

Device Name
IWD-Gel™

Indications for Use *(Describe)*

Rx Indications for Use: The IWD-Gel™ gel is intended to cleanse and moisten the wound bed, providing a moist environment, and is indicated for light to moderately exudating wounds such as:

- diabetic foot ulcers
- leg ulcers (venous stasis ulcers)
- arterial ulcers and leg ulcers of mixed etiology
- pressure ulcers/sores (partial and full thickness)
- 1st and 2nd-degree superficial partial thickness burns
- donor sites, traumatic and surgical wounds

OTC Indications for Use: The IWD-Gel™ gel is intended to cleanse and moisten the wound bed, and for the management of minor cuts, abrasions, minor lacerations, and minor 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.

510(k) Summary

DATE PREPARED
April 6, 2026

MANUFACTURER AND 510(k) OWNER
innovaCorium, Inc.
UF Innovate
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OFFICIAL CONTACT
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DEVICE INFORMATION

Proprietary Name/Trade Name:	IWD-Gel™
Common Name:	Dressing Wound, Drug
Regulation Number:	N/A
Class:	Unclassified
Product Code:	FRO
Review Panel:	General and Plastic Surgery

PREDICATE DEVICE IDENTIFICATION
The IWD-Gel™ is substantially equivalent to the following predicates:

510(k) Number	Predicate Device Name / Manufacturer	Primary Predicate
K173911	Medline Burn and Wound Gel (PluroGel®) / Medline Industries, Inc.	✓
K092086	Amerigel® Wound Dressing Plus/ Amerx Health Care Corporation	

The predicate devices have not been subject to a design related recall.

DEVICE DESCRIPTION
The innovaCorium wound dressing (IWD-Gel™) is a golden brown, scented, semi-transparent gel intended to cleanse and moisten the wound bed. The IWD-Gel™ is made with a non-absorbable hydropolymer, natural surfactants, and preservatives and it helps create and maintain a moist environment.

The IWD-Gel™ is provided non-sterile for single-patient use. It contains a low concentration of surfactants, which trap debris for subsequent removal and rinse off at dressing change, and a preservative with Polyhexamethylene Biguanide (PHMB) and natural components, including *Quercus robur* Extract and Thyme oil, to stabilize the device during storage and extend shelf life.

The IWD-Gel™ was developed for the management of wounds that benefit from a moist wound environment and cleansing. The proprietary formulation includes preservatives to inhibit the growth of microorganisms in the hydrogel within the container, cleansers (surfactants/ dispersants), gelling agents (thickeners), and a moisturizer.

INDICATIONS FOR USE

Rx Indications for Use: *The IWD-Gel™ gel is intended to cleanse and moisten the wound bed, providing a moist environment, and is indicated for light to moderately exudating wounds such as:*

- *diabetic foot ulcers*
- *leg ulcers (venous stasis ulcers)*
- *arterial ulcers and leg ulcers of mixed etiology*
- *pressure ulcers/sores (partial and full thickness)*
- *1st and 2nd-degree superficial partial thickness burns*
- *donor sites, traumatic and surgical wounds*

OTC Indications for Use: *The IWD-Gel™ gel is intended to cleanse and moisten the wound bed, and for the management of minor cuts, abrasion, minor laceration, and minor burns.*

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

innovaCorium believes that the IWD-Gel™ is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has a similar design and dimensions and uses similar materials as the Plurogel® (Medline Burn and Wound Dressing) (K173911) and Amerigel® (K092086) devices. The subject device has the same intended use and similar technological characteristics as the devices cleared in K173911 and K092086.

The operational characteristics of the proposed IWD-Gel™ are identical to the predicate devices in that they are intended to be used as primary or secondary coverings for the management of a variety of wounds. They provide a moist wound environment conducive to wound healing. The

technological characteristics of the proposed IWD-Gel™ and the predicate devices are identical in that they are dressings that include a moist gel-like component and are suitable for the management of a variety of wounds.

	Subject Device	***Primary Predicate Device***	***Secondary Predicate Device***
	IWD-Gel™ innovaCorium	Medline Burn and Wound Gel Medline K173911	AmeriGel® Wound Dressing Plus Amerx Health Corporation K092086
Product Code	FRO	FRO	FRO
Regulation Number	N/A	N/A	N/A
Intended Use	Rx Use: The IWD-Gel™ is intended to cleanse and moisten the wound bed, providing a moist environment, and is indicated for light to moderately exudating wounds, such as: • diabetic foot ulcers • leg ulcers (venous stasis ulcers) • arterial ulcers and leg ulcers of mixed etiology • pressure ulcers/sores (partial and full thickness) • 1st and 2nd degree superficial partial thickness burns • donor sites, traumatic and surgical wounds. OTC Use: The IWD-Gel™ gel is intended to cleanse and moisten the wound bed, and for the management of minor cuts, abrasion, minor laceration, and minor burns.	Medline Burn and Wound Dressing is intended to cleanse and moisten the wound bed for the management of ulcers (including diabetic foot and leg ulcers and pressure ulcers), 1st and 2nd degree burns, partial and full thickness wounds and surgical incisions. It can be used to provide a moist environment that supports autolytic debridement of necrotic tissue.	Indications for Use: • Stage I - IV Pressure ulcers • Venous stasis ulcers. • Ulcerations caused by mixed vascular etiologies • Diabetic skin ulcers • First and second degree bums • Post-surgical incisions • Cuts and abrasions
Configuration	1 oz tube 2 oz. tube 4 oz. tube	1.75 oz. tube	1 oz. tube 3 oz. tube
Design Features	Clear to translucent, water-soluble, virtually odorless amorphous wound gel with a surfactant and PHMB as a preservative.	Clear to translucent, water-soluble, virtually odorless amorphous wound gel with a surfactant and PHMB as a preservative.	Clear to translucent, water-soluble, virtually odorless amorphous wound gel with a surfactant and PEG as a preservative.

Materials	• *Quercus robur* (Oak) Bark Extract • Thyme Oil • PHMB • Decyl Glycoside (polyglycoside) • Poloxamer 188 • Rhamnolipid • Sophorolipid • Hyaluronic Acid • Hydroxyethylcellulose • Polyethylene Glycol 400 • Phenoxyethanol • Water	• PHMB • Glycerin • Poloxamer • Sucrose • Sodium Phosphate Dibasic • Citric Acid • Water	• Oakinn (oak extract) • Meadowsweet extract • Polyethylene glycol (PEG) • Zinc acetate • Lidocaine HCl • Water
Non-clinical testing	• Biocompatibility, in accordance with ISO 10993-1 (breached or compromised surfaces with prolonged contact (>24h to30d) • Shelf-life • USP <51> • USP<61> Microbial Limits • USP <62> Microbiological Examination on Non-Sterile Products • Wound Healing Study • pH • Viscosity • Specific gravity • Loss on drying	• Biocompatibility, in accordance with ISO 10993-1 (breached or compromised surfaces with prolonged contact (>24h to30d) • Shelf-life • USP <51> Antimicrobial Effectiveness • USP<61> Microbial Limits • USP <62> Microbiological Examination on Non-Sterile Products • Wound Healing Study	• Biocompatibility, in accordance with ISO 10993-1 (breached or compromised surfaces with prolonged contact (>24h to30) Biocompatibility, in accordance with ISO 10993-1 (breached or compromised surfaces with prolonged contact (>24h to30d)
Sterile vs. Non-sterile	Non-sterile	Non-sterile	Non-sterile
Reusable vs. Single use	Single use	Single use	Single use

SUMMARY OF NON-CLINICAL TESTING

The following tests were performed to demonstrate safety based on current industry standards:

- pH (USP <791>)
- Viscosity (USP <911>)
- Loss on Drying (USP <731>)
- Specific Gravity (<USP 841>)
- Biocompatibility (ISO 10993-1)
    - Cytotoxicity
    - Sensitization
    - Irritation
    - Acute Systemic Toxicity
    - Material Mediated Pyrogenicity
    - Subacute/Subchronic Toxicity
    - Implantation
- USP <51>
- Shelf-Life
- Non-clinical performance (animal wound healing study)

SUMMARY OF CLINICAL TESTING

Clinical testing was not required.

CONCLUSION

The IWD-Gel™ is considered substantially equivalent to the predicate devices based on the testing performed, the identical indications for use, and similar technological characteristics. Based on the testing performed, including biocompatibility and the non-clinical animal study, it can be concluded that the subject device does not raise new issues of safety or efficacy compared to the predicate devices.