October 26, 2026

Coloplast Corp.
Preeti Jain
Principal Regulatory Specialist
1601 W. River Rd.
Minneapolis, Minnesota 55411

Re: K260285
Trade/Device Name: Triad Hydrophilic Wound Dresssing (1964, 2.5 oz);
Triad Hydrophilic Wound Dressing (1967, 6 oz)
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 23, 2026
Received: September 23, 2026

Dear Preeti Jain:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K260285

Device Name
Triad Hydrophilic Wound Dressing

Indications for Use *(Describe)*

Prescription Use:
Under the supervision of a healthcare professional, Triad Hydrophilic Wound Dressing provides a moist environment conducive to wound healing and is indicated for light to moderately exuding wounds. The Triad Hydrophilic Wound Dressing is intended for management of the following:
- 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 partial thickness burns
- Donor sites, traumatic and surgical wounds.

Non-prescription use:
Triad Hydrophilic Wound Dressing may be used for:
- Minor abrasions
- Minor Lacerations
- Minor cuts
- Minor scalds and 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.

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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"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."

TRADITIONAL 510(k) SUMMARY
[AS REQUIRED BY 21 CFR 807.92]

I. Submitted by:	Coloplast A/S Holtedam1 3050 Humlebaek Denmark
Contact Person:	Preeti Jain Principal Regulatory Affairs Specialist Coloplast Corp. 1601 West River Road North Minneapolis MN 55411 Phone: +1 (612) 413-5614 Email: uspj@coloplast.com
Date of Summary:	Oct 15, 2026
II. Subject Device:	
Trade or Proprietary Name:	Triad Hydrophilic Wound Dressing
Item/Model Numbers:	1964, 1967
Classification Name:	Dressing, Wound, Drug
Device Classification:	Unclassified
Product Code:	FRO
Review Panel:	General & Plastic Surgery
III. Predicate Device:	K101793, Medihoney Wound Gel
Predicate Classification	Unclassified
Predicate Product Code	FRO
IV. Device Description:	Triad Hydrophilic Wound Dressing is a white to slightly off-white sterile paste that has little to no odor. Triad Hydrophilic Wound Dressing helps maintain a moist environment conducive to wound healing and provides support for autolytic debridement. The consistency of the device is particularly suited to dress irregular wounds. It may be used with or without a secondary wound dressing. The product comes in two sizes: 2.5 oz (71g) and 6 oz (170 g), both provided in tubes.

V. Indications for Use:

Prescription Use:

Under the supervision of a healthcare professional, Triad Hydrophilic Wound Dressing provides a moist environment conducive to wound healing and is indicated for light to moderately exuding wounds. The Triad Hydrophilic Wound Dressing is intended for management of the following:

- 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 partial thickness burns
- Donor sites, traumatic and surgical wounds.

Non-prescription use:

Triad Hydrophilic Wound Dressing may be used for:

- Minor abrasions
- Minor Lacerations
- Minor cuts
- Minor scalds and burns

VI. Summary of Technological Characteristics:

The subject and predicate device are both products for topical use with the same intended use.

	Subject Device	**Predicate Device**
Product	**Triad Hydrophilic Wound Dressing**	**MediHoney Gel (K101793)**
510(k) Number	Unassigned	K101793
Intended Use	The dressing helps maintain a moist environment conducive to wound healing and provides support for autolytic debridement.	The dressing helps maintain a moist environment conducive to wound healing and helps aid and support autolytic debridement.
Indications for Use	Prescription Use: Under the supervision of a healthcare professional, Triad Hydrophilic Wound Dressing provides a moist environment conducive to wound healing and is indicated for light to moderately exuding wounds.	Prescription Use: Under the supervision of a healthcare professional, MediHoney Wound Gel Dressing provide a moist environment conducive to wound healing and are indicated for light to moderate exuding wounds.

	Subject Device	Predicate Device
Product	**Triad Hydrophilic Wound Dressing**	**MediHoney Gel (K101793)**
	Triad Hydrophilic Wound Dressing is intended for the management of the following: • 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 partial thickness burns • Donor sites, traumatic and surgical wounds. Non-Prescription Use: Triad Hydrophilic Wound Dressing may be used for: • Minor abrasions • Minor Lacerations • Minor cuts • Minor scalds and burns	The MediHoney Gel Wound Dressing are intended for the management of the following: 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 partial thickness burns, donor sites, traumatic and surgical wounds. Over the counter use: For over-the-counter use, Medihoney Gel Dressings with Active Manuka Honey may be used for: Minor abrasions, lacerations, minor cuts minor scalds and burns
Contra-indications	• Third degree burns • Infected wounds • Patients who have a known sensitivity to cellulose gum (CMC) or any other component in Triad	• Third degree burns • Patients who have a known sensitivity to honey or any other component parts specific to each dressing
Condition of Use	Single use Multiple uses for single patient	Single use
Sterility	Sterile	Sterile
Performance Characteristics	Ensure provision of a moist environment by absorption and creation of a physical barrier	Ensure moisture by attractive fluid by osmolarity and absorbing by the gelling ingredients

VII. Performance Data:

Non-clinical tests including viscosity, moisture absorbency, water activity, physical barrier properties, and sterile barrier integrity were performed to support the safety and effectiveness of the device. Shelf-life stability, in use stability and transportation testing were successfully completed to provide evidence that products can withstand transportation and will perform as intended to the end-of-shelf-life.
Complete battery of Biocompatibility end point testing was completed and evaluated in accordance with ISO-10993-1 and has been shown to meet the criteria for the relevant endpoints.

In addition, an animal wound healing study was conducted to evaluate local tissue effects and wound healing performance of the subject and predicate device wound dressings. The study found that Triad Hydrophilic Wound dressing performed similarly to the predicate device and that both the dressings did not have an effect on the wound healing process.

VIII. Conclusions:

The subject device K260285 demonstrates substantially equivalence to the predicate device (K101793) with respect to indications for use, overall design and technological characteristics. The differences between the subject and predicate device do not raise new questions of safety or effectiveness of use of the subject device.