March 22, 2024

Coloplast Corp.
Laura Kelly
Principal Regulatory Affairs Specialist
1601 West River Road North
Minneapolis, Minnesota 55411

Re: K231953
Trade/Device Name: Biatain Fiber Ag (33570 - 5 cm x 5 cm / 2 in x 2 in); Biatain Fiber Ag (33572 - 10 cm x 12 cm / 4 in x 5 in); Biatain Fiber Ag (33574 - 15 cm x 15 cm / 6 in x 6 in); Biatain Fiber Ag (33576 - 2.5 cm x 46 cm / 1 in x 18 in); Biatain Fiber Ag (33578 - 20 cm x 30 cm / 8 in x 12 in)
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 22, 2024
Received: February 22, 2024

Dear Laura Kelly:

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); 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.

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 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

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)*
K231953

Device Name
Biatain Fiber Ag

Indications for Use *(Describe)*

The product is indicated for use on moderate to highly exuding acute and chronic wounds such as:

- Diabetic ulcers
- Leg ulcers (arterial ulcers, venous ulcers and leg ulcers of mixed etiology)
- Pressure injuries (stage 2-4)
- Traumatic wounds
- Partial thickness (second degree) burns
- Donor sites
- Post-operative surgical wounds
- Exudate absorption in oncology wounds, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma

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.

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TRADITIONAL 510(k) SUMMARY

Submitted by:	Coloplast A/S Holtedam 1 3050 Humlebaek Denmark
Contact Person:	Laura Kelly Principal Regulatory Affairs Specialist Coloplast Corp. 1601 West River Road North Minneapolis MN 55411 Phone: +1 (612) 940-9983 Email: uslke@coloplast.com

Date of Summary:	March 22, 2024

SUBJECT DEVICE

Trade or Proprietary Name:	Biatain Fiber Ag
Classification Name:	Dressing, Wound, Drug
Device Classification:	Unclassified
Product Code:	FRO
Review Panel:	General & Plastic Surgery
Predicate Device:	K173675, AQUACEL™ Ag+ EXTRA Enhanced Hydrofiber™ Dressing with Silver and Strengthening Fiber
Device Description:	Biatain Fiber Ag is a soft, sterile, primary wound dressing made mainly from non-woven gelling carboxymethyl cellulose (CMC) fibers. In addition, non-gelling bicomponent (BiCo) fibers are incorporated to obtain strength and integrity of the products both in dry and gelled condition. Ionic silver (Ag+) is added for antimicrobial efficacy within the dressing, and ethyl lauroyl arginate (LAE) is added as combined surfactant and chelator within the dressing.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

	Subject device **Biatain Fiber Ag (K231953)**	**Predicate device** **AQUACEL Ag+ EXTRA (K173675)**
Indications for Use	The product is indicated for use on moderate to highly exuding acute and chronic wounds such as: • Diabetic ulcers • Leg ulcers (arterial ulcers, venous ulcers and leg ulcers of mixed etiology) • Pressure injuries (stage 2-4) • Traumatic wounds • Partial thickness (second degree) burns • Donor sites • Post-operative surgical wounds • Exudate absorption in oncology wounds, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma Prescription use only.	Over-the-Counter Use: AQUACEL™ Ag+ EXTRA Enhanced Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for the management of: • Abrasions • Lacerations • Minor cuts • Minor scalds and burns Prescription Use: Under the supervision of a healthcare professional: AQUACEL™ Ag+ EXTRA Enhanced Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for the management of: • Wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection; • Partial thickness (second degree) burns; Diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness); • Surgical wounds left to heal by secondary intention such as dehisced surgical incisions; • Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g., orthopedic and vascular); • Traumatic wounds; • Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites; • Oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma; • Management of painful wounds; • Infected wounds
Components	• Composed of sodium carboxymethyl cellulose (CMC) fibers with bicomponent (BiCo) fibers and 0.63% (w/w) ionic silver with ethyl lauroyl arginate (LAE). • The device is reinforced with BiCo fibers embossed to create a hexagon pattern.	• Composed of sodium carboxymethylcellulose (Hydrofiber™) and 1.2% ionic silver with EDTA and benzethonium chloride.
Mode of action	• The dressing absorbs exudate and forms a gel. The gelled dressing retains exudate, thereby maintaining a moist wound environment to support the healing process. • The dressing aids in the removal of unnecessary material from the wound (autolytic debridement).	• The dressing absorbs wound fluid and creates a soft, conformable gel, which maintains a moist wound environment to support the healing process. • The dressing aids in the removal of unnecessary material from the wound (autolytic debridement) without damaging newly formed tissue.

	• When the wound exudate is absorbed by the Biatain Fiber Ag dressing, the free ionic silver exerts its activity by killing the microorganisms held within the dressing.	• The silver preservative in the dressing reduces the growth of microorganisms within the dressing. • The silver preservative in the dressing kills wound bacteria held in the dressing and provides an effective barrier to bacterial penetration of the dressing.
Characteristics	• Sterile. • Absorbs exudate. • Forms a conformable gel • The preservative action of ionic silver reduces bacterial growth within the dressing. • Should be used with a secondary dressing depending on the clinical condition of the wound.	• Sterile. • Absorbs exudate (including bacteria) or blood. • Forms a soft conformable gel. • Ionic silver within the dressing functions as a preservative to reduce bacterial growth within the dressing. • May require a secondary dressing.

The differences in technological characteristics of the subject device do not raise additional questions of safety and effectiveness.

PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility: A biocompatibility evaluation, in accordance with ISO 10993-1:2018, has been conducted and concludes that the dressings have a safe toxicological profile for their intended use. The battery of testing included the following tests:

- Cytotoxicity
- Irritation
- Sensitization
- Acute systemic toxicity
- Sub-acute systemic toxicity
- Pyrogenicity
- Implantation

Bench Testing: Testing of physical/mechanical properties has been conducted on key performance parameters:

- Absorption capacity
- Fluid retention capacity
- Wet strength (gelled condition)
- Lateral shrinkage upon absorption
- Volume expansion upon absorption
- Lateral spreading of fluid

Antimicrobial Effectiveness within the Dressing:	The preservative action of silver and LAE reduces bacterial growth within the dressing. This was confirmed by *in vitro* tests. ≥4 log reduction (AATCC 100) antimicrobial effectiveness against 9 organisms, 3 Gram positive bacteria, 4 Gram negative bacteria, 1 yeast, and 1 mold for up to 7 days within the dressing.
Animal Study:	A full thickness wound healing model in porcine study was conducted to evaluate local tissue effects and wound healing performance of a wound dressing containing silver (Biatain Fiber Ag). The study demonstrated that Biatain Fiber Ag and the predicate device did not hinder the wound healing process.

CONCLUSION

Based on the identical indications for use, principles of operations, technological characteristics, and performance testing, Biatain Fiber Ag is as safe and as effective as the predicate device, ConvaTec's AQUACEL™ Ag+ EXTRA Enhanced Hydrofiber™ Dressing with Silver and Strengthening Fiber (K173675).