February 21, 2020

Coloplast A/S
Lykke Forchhammer
Director of RA
Holtedam 1
Humlebaek, 3050 Dk

Re: K191536
Trade/Device Name: Biatain Silicone Ag
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 16, 2020
Received: January 21, 2020

Dear Lykke Forchhammer:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Kimberly M. Ferlin, Ph.D.
Assistant Director (Acting)
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191536

Device Name
Biatain Silicone Ag

Indications for Use *(Describe)*
Biatain® Silicone Ag is intended to provide a moist wound environment and exudate management of acute and chronic wounds.
Biatain® Silicone Ag is indicated for the management of exuding leg and foot ulcers, pressure ulcers, diabetic foot ulcers, superficial and partial thickness burns, donor sites, and, traumatic and post-operative wounds.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

5. TRADITIONAL 510(K) SUMMARY

Submitted by:	Coloplast A/S Holtedam 1 3050 Humlebaek Denmark
Contact Person:	Lykke Forchhammer Director of RA Innovation and Market Expansion Coloplast A/S Holtedam 1 3050 Humlebaek Denmark Telephone: 0045-49111271 Email: dklfo@coloplast.com
Date of Summary:	21 February 2020
Trade or Proprietary Name:	Biatain® Silicone Ag
Common or Usual Name:	Dressing, Wound, Drug
Classification and CFR:	Unclassified
Product Code:	FRO
Review Panel:	General and Plastic Surgery
Predicate Device:	K100218, Biatain® Ag (Coloplast A/S)
Reference Device:	K120828, Biatain® Silicone Ag (Coloplast A/S)

Device Description:

The device is available as sterile, single use only. The device is intended to provide a moist environment and exudate management of acute and chronic wounds. The device maintains a moist wound providing the optimal environment for wound healing.

The device consists of:

- Polyurethane (PU) top film – a 25 µm semi-permeable barrier, printed with grey dots.
- Absorbing pad - composed of a 3.0 mm PU foam containing an anti-bacterial silver complex (silver sodium hydrogen zirconium phosphate).
- Silicone adhesive bi-layer - composed of a middle PU film with a silicone adhesive gel. The PU top film and the middle PU film are laminated together at the border.
- Protective film – composed of three or five parts; the center part and the remaining side parts.

The device:

- contains a silver compound (silver sodium hydrogen zirconium phosphate). In vitro testing demonstrated that Biatain® Silicone Ag has an antimicrobial effect in the dressing against the following strains of 3 gram positive bacteria, 3 gram negative bacteria, 1 yeast, and 1 mold: *Staphylococcus aureus, Enterococcus faecalis, Streptococcus pyogenes, Proteus mirabilis, Klebsiella pneumoniae, Escherichia coli, Aspergillus brasiliensis* and *Meyerozyma guilliermondii*. The dressing sustains antimicrobial activity for up to 7 days.

The device may be used in hospitals, healthcare facilities, and home care.

Sterilized using ethylene oxide (EO).

Prescription Use Only.

Indications for Use:	Biatain® Silicone Ag is intended to provide a moist wound environment and exudate management of acute and chronic wounds. Biatain® Silicone Ag is indicated for the management of exuding leg and foot ulcers, pressure ulcers, diabetic foot ulcers, superficial and partial thickness burns, donor sites, and, traumatic and post-operative wounds.
Technological Characteristics:	The subject device is substantially equivalent to the predicate device based upon the information below. .

	Subject Device **Biatain® Silicone Ag**	**Predicate Device** **Biatain® Ag**	**Reference Device:** **Biatain® Silicone Ag**
510(k) Submitter	Coloplast A/S	Same	Same
510(k) Number	K191536	K100218	K120828
Regulatory Class	Unclassified	Same	Same
Classification Name	Dressing, Wound, Drug	Same	Same
Product Code	FRO	Same	Same
Intended Use	Biatain® Silicone Ag is intended to provide a moist wound environment and exudate management.	Same	Same

	Subject Device **Biatain® Silicone Ag**	**Predicate Device** **Biatain® Ag**	**Reference Device:** **Biatain® Silicone Ag**
Indications for Use	Biatain® Silicone Ag is intended to provide a moist wound environment and exudate management of acute and chronic wounds. Biatain® Silicone Ag is indicated for the management of exuding leg and foot ulcers, pressure ulcers, diabetic foot ulcers, superficial and partial thickness burns, donor sites, and, traumatic and post-operative wounds.	Biatain Ag foam dressings are indicated for wounds with moderate to high amounts of exudate, including leg ulcers and Category II-IV pressure ulcers with delayed healing due to bacteria, or where there is a risk of infection. Biatain Ag foam dressings may be used for second-degree burns, donor sites, postoperative wounds and skin abrasions with delayed healing due to bacteria, or where there is a risk of infection. Biatain Ag non-adhesive foam dressings are additionally indicated for diabetic foot ulcers. Biatain Ag foam dressings may reduce odor caused by micro-organisms in the wound. Biatain Ag foam dressings may be used to support moist wound healing on patients who are in treatment for a local or systemic infection under the discretion of a healthcare professional. Depending on the prognosis of the wound, Biatain Ag foam dressings may be used throughout the healing process to provide protection for the indicated types of wounds. Biatain Ag foam dressings are suitable for use in combination with compression therapy. Biatain Ag foam filler/cavity is indicated for deep exuding wounds, including leg ulcers, pressure ulcers, diabetic foot ulcers and acute wounds.	Biatain® Silicone Ag Foam Dressings are indicated for the management of moderately to highly exuding leg ulcers and pressure sores. The dressing can also be used for 2nd degree burns, donor sites, postoperative wounds, and skin abrasions.
Prescription Device	Yes	Same	Same
Single Use	Yes	Same	Same
Sterile Device	Yes	Same	Same
Method of Sterilization	EO SAL 10^{-6}	Irradiated SAL 10^{-6}	Same (EO) SAL 10^{-6}

	Subject Device **Biatain® Silicone Ag**	**Predicate Device** **Biatain® Ag**	**Reference Device:** **Biatain® Silicone Ag**
Recommended Wear Time	Up to 7 days. Repeated use of the device should not exceed 30 days	Same	Same
Shelf Life	2-years	3-years	3-years
Silver (Ag)	Silver Compound (Ionic) [silver sodium hydrogen zirconium phosphate]	Same	Same
Silver Content	0.95 mg/cm^2	Same	Same
Silver Release (within the dressing)	24 h: 207 – 367 µg/cm^2 48 h: 350 – 589 µg/cm^2 72 h: 439 – 726 µg/cm^2 96 h: 500 – 813 µg/cm^2 168 h: 591 – 937 µg/cm^2	Same	Same

	Subject Device **Biatain® Silicone Ag**	**Predicate Device** **Biatain® Ag**	**Reference Device:** **Biatain® Silicone Ag**
Antimicrobial Effectiveness within the Dressing	Fulfills both ≥4 log reduction (AATCC 100) as described below: Fulfills ≥4 log reduction (AATCC 100) for antimicrobial effect against 3 gram positive bacteria, 3 gram negative bacteria, 1 yeast, and 1 mold: S*taphylococcus aureus, Enterococcus faecalis, Streptococcus pyogenes, Proteus mirabilis, Klebsiella pneumoniae, Escherichia coli, Aspergillus brasiliensis* and *Meyerozyma guilliermondii.*	Effective antimicrobial activity within the dressing.	Effective antimicrobial activity within the dressing.
Primary Packaging	Paper/Polyester Film	Biatain® Ag Non-adhesive: White Polyester Film/Transparent Polyester Film Biatain® Ag Adhesive: Foil	Tyvek/Transparent Foil

	Subject Device **Biatain® Silicone Ag**	**Predicate Device** **Biatain® Ag**	**Reference Device:** **Biatain® Silicone Ag**
Top Film	Vapor permeable polyurethane (PU) top film	Same	Same
Pigment: **Top Film Colorant**	CI Pigment Black 7 Titanium dioxide Aluminum hydroxide	Black iron oxide Titanium dioxide C.I Pigment Black 7	Black iron oxide Titanium dioxide
Pigment: **Top Film Dots**	C.I. Pigment White 6 C.I. Pigment Black 7 Titanium chelates Aluminum oxide	Not Applicable	Not Applicable
Pigment: **Top Film Logo**	CI Pigment Black 7	Not Applicable	Not Applicable
Absorbaent Polyurethane Foam with Silver Compound	Polyurethane (PU) foam with silver complex (silver sodium hydrogen zirconium phosphate)	Same	Same and contains hotmelt Pressure Sensitive Adhesive (PSA)
Polyurathane Foam Thickness	3.0 mm PU foam with silver complex	3.0 mm and 4.4 mm PU foam with silver complex	Same (3.0 mm PU foam with silver complex)
Adhesive Bilayer	Silicone adhesive bi-layer across the device with perforations across the absorbent pad	Biatain® Ag Non-adhesive Dressings have no adhesive layer. Biatain® Ag Adhesive: Hydrocolloid adhesive border	Perforated Silicone adhesive bi-layer on the border
Protective Film (Release Liner)	Polypropylene (PP) 3 and 5-piece design	Polyethylene (PE) 2 and 3-piece design	Polyethylene (PE) 3-piece design
Device Sizes and Shapes.	Square: 7.5 x 7.5 cm 10 x 10 cm 12.5 x 12.5 cm 15 x 15 cm 17.5 x 17.5 cm	Square: 10 x 10 cm (non-adhesive) 12.5 x 12.5 cm (adhesive) 15 x 15 cm (non-adhesive) 18 x 18 cm (adhesive) 20 x 20 cm (non-adhesive)	Square: 7.5 x 7.5 cm 10 x 10 cm 12.5 x 12.5 cm

	Subject Device **Biatain® Silicone Ag**	**Predicate Device** **Biatain® Ag**	**Reference Device:** **Biatain® Silicone Ag**
	Rectangle: 10 x 20 cm 10 x 30 cm	Rectangle: 5 x 7 cm 10 x 20 cm	Not Applicable
	Heel: 18 x 18 cm	Heel: 19 x 20 cm	Not Applicable
	Sacral: 15 x 19 cm 25 x 25 cm	Sacral: 23 x 23 cm	Not Applicable

Performance Data:	Performance testing for the Biatain® Silicone Ag device was conducted according to applicable sections of voluntary standards in order to document the following properties of the subject device. The proposed changes do not impact the performance specifications: • Real Time and Accelerated Aged shelf life testing [per ASTM F1980-07 (2011)] • Packaging transportation and integrity testing per ASTM D4169-16 • Biocompatibility according to ISO 10993-1 (2009) • Free swelling absorptive capacity, wear time, border permeability, and Fluid Handling Capacity (absorption and moisture vapour transmission rate) per EN 13726-1:2002/AC2003 • Waterproofness per EN 13726-3:2002 • Dynamic Friction of the PU Film per EN ISO 8295 1 2004 • Conformability to body per EN 13726-4:2003 • Ease of release - peel adhesion per ASTM D3330/D3330M-04 Method A • Antimicrobial effectiveness per modified ATTCC 100:2012 All tests passed the pre-determined acceptance criteria.
Clinical Data	No clinical data was required to support substantial equivalence.
Substantial Equivalence Conclusion:	Based on the same intended use with no new patient population or wound type, similar technological characteristics and materials, and performance testing, Coloplast believes the proposed Biatain® Silicone Ag is substantially equivalent to the predicate device Biatain® Ag (K100218), and the reference device, Biatain® Silicone Ag (K120828).