March 13, 2020

Molnlycke Health Care, US LLC
Leonard Stewart
Regulatory Affairs Specialist
5550 Peachtree Parkway, Suite 500
Norcross, Georgia 30092

Re: K191869
Trade/Device Name: Biogel PI UltraTouch S Surgical Glove with a Low Dermatitis Potential Claim, Biogel PI UltraTouch S Indicator Underglove with a Low Dermatitis Potential Claim
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO
Dated: February 17, 2020
Received: February 18, 2020

Dear Leonard Stewart:

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,

Elizabeth Claverie, M.S.
Assistant Director
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)*

K191869

Device Name

Biogel® PI UltraTouch S Surgical Glove with a Low Dermatitis Potential Claim and Biogel® PI UltraTouch S Indicator Underglove with a Low Dermatitis Potential Claim

Indications for Use *(Describe)*

The Biogel® PI UltraTouch S Surgical Glove with a Low Dermatitis Potential Claim is a disposable device made of polyisoprene, that is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious material and other contaminants.

The Biogel® PI UltraTouch S Indicator Underglove with a Low Dermatitis Potential Claim is a disposable device made of polyisoprene, blue in color, that is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious material and other contaminants

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.

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510(k) SUMMARY (K191869)

for

Biogel® PI UltraTouch S Surgical Glove with Low Dermatitis Potential Claim

and Biogel® PI UltraTouch S Indicator Underglove with Low Dermatitis Potential Claim

Date Prepared:	March 11, 2020
Submission Sponsor:	Mölnlycke Health Care US, LLC 5550 Peachtree Parkway, Suite 500 Norcross, GA 30092 Registration number: 3004763499 Owner/Operator Number: 8030877
Submission Correspondent:	Leonard Stewart Regulatory Affairs Specialist Tel: 470-375-0178 Fax: 678-245-7746 email: leonard.stewart@molnlycke.com
Trade/Proprietary Names:	Biogel® PI UltraTouch S Surgical Glove with a Low Dermatitis Potential Claim and Biogel® PI UltraTouch S Indicator Underglove with a Low Dermatitis Potential Claim
Regulation Name:	Non-powered surgeon's glove
Common Name:	Surgeon's Glove
Classification Name:	Surgeon's Glove
Device Class:	Class I
Regulation Number:	21 CFR 878.4460
Product Code:	KGO
510(k) Submission Number:	
Predicate Device Name(s):	Biogel® PI UltraTouch S Surgical Glove and Biogel® PI UltraTouch S Indicator Underglove (K190077)

Description of Device:

Subject of this submission are two surgical gloves: a single-use, sterile, straw-colored overglove which is a disposable, powder-free surgical glove made from synthetic polyisoprene, and a single-use, sterile, blue underglove which is a disposable, powder-free surgical glove made from synthetic polyisoprene. The overglove, and underglove may be used independently or worn as a double-gloving pair if desired.

Indications for Use:

The Biogel® PI UltraTouch S Surgical Glove with a Low Dermatitis Potential Claim is a disposable device made of polyisoprene, that is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious material and other contaminants.

The Biogel® PI UltraTouch S Indicator Underglove with a Low Dermatitis Potential Claim is a disposable device made of polyisoprene, blue in color, that is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious material and other contaminants

Technological Characteristics:

	Summary of technological characteristics of the subject device compared to the predicate device					
	(overglove)			**(underglove)**		
	Biogel® PI UltraTouch S Surgical Glove with Low Dermatitis Potential Claim (Subject Device)	**Biogel® PI UltraTouch S Surgical Glove (Predicate Device)**	**Comment**	**Biogel® PI UltraTouch S Indicator Underglove with Low Dermatitis Potential Claim (Subject Device)**	**Biogel® PI UltraTouch S Indicator Underglove (Predicate Device)**	**Comment**
510(k) Number	K191869	K190077	-	K191869	K190077	-
Manufacturer	Mölnlycke	Mölnlycke	Identical	Mölnlycke	Mölnlycke	Identical
Regulation number	21CFR 878.4460	21CFR 878.4460	Identical	21CFR 878.4460	21CFR 878.4460	Identical
Regulation name	Surgeon's Glove	Surgeon's Glove	Identical	Surgeon's Glove	Surgeon's Glove	Identical
Regulatory class	Class 1	Class 1	Identical	Class 1	Class 1	Identical
Product code	KGO	KGO	Identical	KGO	KGO	Identical
Intended use	Powder-Free Surgeon's Glove	Powder-Free Surgeon's Glove	Identical	Powder-Free Surgeon's Glove	Powder-Free Surgeon's Glove	Identical
Indication for use	Biogel® PI UltraTouch S Surgical Glove with a low dermatitis potential claim is a disposable device made of polyisoprene, that is intended to be worn on the hands, usually in surgical settings, to provide a barrier against	Biogel® PI UltraTouch S Surgical Glove is a disposable device made of polyisoprene, that is intended to be worn on the hands, usually in surgical settings, to provide a barrier against	Same	Biogel® PI UltraTouch S Indicator Underglove with a low dermatitis potential claim is a disposable device made of polyisoprene, blue in color that is intended to be worn on the hands, usually in surgical settings, to provide a barrier against	Biogel® PI UltraTouch S Indicator Underglove is a disposable device made of polyisoprene, blue in color that is intended to be worn on the hands, usually in surgical settings, to provide a barrier against	Same

	Summary of technological characteristics of the subject device compared to the predicate device					
	potentially infectious material and other contaminants	potentially infectious material and other contaminants		potentially infectious material and other contaminants	potentially infectious material and other contaminants	
Low Dermatitis Potential Claim	Low dermatitis potential: reduced potential for sensitizing users to chemical additives	-	-	Low dermatitis potential: reduced potential for sensitizing users to chemical additives	-	-
Material	Synthetic Polyisoprene	Synthetic Polyisoprene	Identical	Synthetic Polyisoprene	Synthetic Polyisoprene	Identical
Design	Single use	Single use	Identical	Single use	Single use	Identical
	Sterile	Sterile	Identical	Sterile	Sterile	Identical
	Powder-free	Powder-free	Identical	Powder-free	Powder-free	Identical
	Hand specific	Hand specific	Identical	Hand specific	Hand specific	Identical
	Beaded Cuff	Beaded cuff	Identical	Beaded cuff	Beaded cuff	Identical
Coating	Yes	Yes	Identical	Yes	Yes	Identical
Color	Straw (Natural)	Straw (Natural)	Identical	Blue	Blue	Identical
Sterilization method	Radiation	Radiation	Identical	Radiation	Radiation	Identical
Sterility Assurance Level (SAL)	10^{-6} SAL	10^{-6} SAL	Identical	10^{-6} SAL	10^{-6} SAL	Identical
Dimensions & physical properties	Meets ASTM D3577-09(2015)	Meets ASTM D3577-09(2015)	Identical	Meets ASTM D3577-09(2015)	Meets ASTM D3577-09(2015)	Identical
Freedom from holes	AQL meets 21 CFR 800.20 and ASTM D3577-09(2015) requirements	AQL meets 21 CFR 800.20 and ASTM D3577-09(2015) requirements	Identical	AQL meets 21 CFR 800.20 and ASTM D3577-09(2015) requirements	AQL meets 21 CFR 800.20 and ASTM D3577-09(2015) requirements	Identical
Powder residual	Meets requirements of ≤ 2.0 mg/glove for Powder-free designation per ASTM D3577-09(2015)	Meets requirements of ≤ 2.0 mg/glove for Powder-free designation per ASTM D3577-09(2015)	Identical	Meets requirements of ≤ 2.0 mg/glove for Powder-free designation per ASTM D3577-09(2015)	Meets requirements of ≤ 2.0 mg/glove for Powder-free designation per ASTM D3577-09(2015)	Identical

Summary of Non-Clinical/Clinical Testing:

Summary of Non-Clinical Testing			
	Standard/Test/FDA Guidance	**Biogel® PI UltraTouch S Surgical Glove with Low Dermatitis Potential Claim (Subject Device)**	**Biogel® PI UltraTouch S Indicator Underglove with Low Dermatitis Potential Claim (Subject Device)**
Biocompatibility:			
Primary Skin Irritation	ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	Under the conditions of the study, not an irritant.	
ISO Closed Patch Sensitization	ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	Under the conditions of the study, not a sensitizer.	
Acute Systemic Toxicity Study	ISO 10993-11:2010 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	Under the conditions of the study, no mortality or evidence of systemic toxicity from the extracts.	
Performance Test:			
Low Dermatitis Potential	Modified Draize-95 Test	Under the conditions of the study, the subject devices demonstrated Low dermatitis potential: reduced potential for sensitizing users to chemical additives	
Physical characteristics:			
Dimensions	ASTM D3577- 09(2015) Standard Specification for Rubber Surgical Gloves	Meets ASTM D3577-09(2015) requirements for length, width, and thickness. Identical to predicate.	
Physical Properties	ASTM D3577- 09(2015) Standard Specification for Rubber Surgical Gloves	Meets ASTM D3577-09(2015) requirements for tensile strength and elongation at break before and after accelerated aging. Identical to Predicate.	
Freedom from holes	ASTM D5151-06(2015) Standard Test Method for Detection of Holes in Medical Gloves ASTM D3577- 09(2015) Standard Specification for Rubber Surgical Gloves	Exceeds 21 CFR 800.20 and ASTM D3577-09(2015) requirements of AQL 1.5. Identical to predicate.	
Powder residual	ASTM D6124-06(2017) Standard Test Method for Residual Powder on Medical Gloves ASTM D3577- 09(2015) Standard Specification for Rubber Surgical Gloves	Meets powder level requirements for "Powder-free" designation per ASTM D3577-09(2015). Identical to predicate.	

Clinical Data Summary			
	Biogel® PI UltraTouch S Surgical Glove with Low Dermatitis Potential Claim (Subject Device), Biogel® PI UltraTouch S Indicator Underglove with Low Dermatitis Potential Claim (Subject Device)	**Biogel® PI UltraTouch S Surgical Glove (Predicate Device), Biogel® PI UltraTouch S Indicator Underglove (Predicate Device)**	**Comment**
Clinical testing	Clinical data was not required	Clinical data was not required	Identical

Conclusion:

The conclusions drawn from the nonclinical test for Biogel® PI UltraTouch S Surgical Glove with a low dermatitis potential claim and Biogel® PI UltraTouch S Indicator Underglove with a low dermatitis potential claim demonstrates that these subject devices are as safe, as effective, and perform as well or better than the legally marketed predicate devices Biogel® PI UltraTouch S Surgical Glove and Biogel® PI UltraTouch S Indicator Underglove (K190077).