DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 31, 2015

MÖLNLYCKE HEALTH CARE US, LLC
Ms. Megan Bevill
Manager, Regulatory Affairs
5550 Peachtree Parkway, Suite 500
Norcross, GA 30092

Re: K150146
Trade/Device Name: Biogel® PI Micro Indicator Underglove
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's glove
Regulatory Class: I
Product Code: KGO
Dated: July 31, 2015
Received: August 4, 2015

Dear Ms. Bevill:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150146

Device Name

Biogel® PI Micro Indicator Underglove

Indications for Use *(Describe)*

The Biogel® PI Micro Indicator Underglove 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.

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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510(k) SUMMARY

This 510(k) summary information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Date Prepared: July 31, 2015

Applicant:
Mölnlycke Health Care US, LLC
5550 Peachtree Parkway, Suite 500
Norcross, GA 30092
Registration number: 3004763499
Owner/Operator Number: 8030877

Official Correspondent:
Megan Bevill
Manager, Regulatory Affairs
Tel: 470-375-0049
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Trade/Proprietary Names: Biogel® PI Micro Indicator Underglove

Regulation Name: Surgeon's Glove

Device Class: Class I

Regulation Number: 21 CFR 878.4460

Product Code: KGO

Predicate Device Name(s): Biogel® PI Indicator® Underglove (K111413)

Reason for 510(k) Submission:

This premarket notification has been prepared to obtain clearance for a new surgeon's glove, the Biogel® PI Micro Indicator Underglove. The subject device is a new addition to our surgical glove product portfolio and is similar in design to the Biogel® PI Indicator® Underglove, previously cleared under premarket notification K111413.

Description of Device:

The subject device is a single-use disposable powder-free surgical glove that is supplied sterile and made from synthetic polyisoprene material (not made from natural rubber latex).

Intended Use/Indication for Use:

The Biogel® PI Micro Indicator Underglove 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 device compared to the predicate device		
	Biogel® PI Micro Indicator Underglove	**Biogel® PI Indicator® Underglove**
510(k) clearance	K150146	K111413
Manufacturer	Mölnlycke	Mölnlycke
Regulation number	21CFR 878.4460	21CFR 878.4460
Regulation name	Surgeon's Glove	Surgeon's Glove
Regulatory class	Class 1	Class 1
Product code	KGO	KGO
Intended use	Powder-Free Surgeon's Glove	Powder-Free Surgeon's Glove
Indication for use	Biogel® PI Micro Indicator Underglove is a disposable device made of polyisoprene, blue in color, that is intended to be worn on the hands, usually in surgical setting, to provide a barrier against potentially infectious material and other contaminants.	Biogel® PI Indicator® Underglove is a disposable device made of polyisoprene, blue in color, that is intended to be worn on the hands, usually in surgical setting, to provide a barrier against potentially infectious material and other contaminants.
Material	Synthetic Polyisoprene	Synthetic Polyisoprene
Design	Single use	Single use
	Sterile	Sterile
	Powder-free	Powder-free
	Hand specific	Hand specific
	Beaded cuff	Beaded cuff
Coating	No	Yes
Colour	Blue	Blue
Sterilisation method	Radiation	Radiation
Sterility Assurance Level (SAL)	10^{-6} SAL	10^{-6} SAL
Dimensions & physical properties	Meets ASTM D3577	Meets ASTM D3577
Freedom from holes	AQL meets 21 CFR 800.20 and ASTM D3577 requirements	AQL meets 21 CFR 800.20 and ASTM D3577 requirements
Powder residual	Meets requirements of ≤ 2.0 mg/glove for Powder-free designation per ASTM D3577	Meets requirements of ≤ 2.0 mg/glove for Powder-free designation per ASTM D3577
Performance Test Data Summary - Subject Device (modified version of the predicate)		
	Standard/Test/FDA Guidance	**Results Summary**
Biocompatibility :		
Primary Skin Irritation	ISO 10993-10	Under the conditions of the study, not an irritant.

ISO Closed Patch Sensitization	ISO 10993-10	Under the conditions of the study, not a sensitizer.
Physical characteristics :		
Dimensions	ASTM D3577	Meets ASTM D3577 requirements for length, width, and thickness
Physical Properties	ASTM D3577	Meets ASTM D3577 requirements for tensile strength and elongation at break before and after accelerated aging
Freedom from holes	21 CFR 800.20 and ASTM D3577, tested according to ASTM D5151	Exceeds 21 CFR 800.20 and ASTM D3577 requirements of AQL 1.5
Powder residual	ASTM D3577 tested according to ASTM D6124	Meets powder level requirements for "Powder-free" designation per ASTM D3577
Clinical Data Summary - Subject Device (modified version of the predicate)		
Clinical testing :	Clinical data is not required	

Conclusion:

The subject devices are substantially equivalent to the Biogel® PI Indicator® Underglove previously cleared under K111413 with respect to design, technological characteristics, intended use, and conformance to standard requirements.