June 27, 2019

LDI Corporation
% Gary Syring
Principal Consultant
Quality & Regulatory Associates, LLC
800 Levanger Lane
Stoughton, Wisconsin 53589

Re: K190782
Trade/Device Name: FlexGard Cut-Resistant Glove Liners
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I
Product Code: KGO
Dated: March 22, 2019
Received: March 27, 2019

Dear Gary Syring:

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,

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
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)*
K190782

Device Name
FlexGard® Cut-Resistant Glove Liners

Indications for Use *(Describe)*

The FlexGard® Cut-Resistant Glove Liners are single use glove liners intended to help with protection against cuts when used with an inner and outer surgical glove. The glove liner must be worn between two surgical gloves.

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 – K190782

This summary is provided to support the 510(k) pre-market notification for the FlexGard® Cut-Resistant FlexGard Liners, as accessories to surgical gloves.

Company Name:	LDI Corporation 3560 Lafayette Road Building 2, Suite C Portsmouth, NH 03801
Company Contact:	Lou LaMarca, CEO LDI Corporation Phone: 603-436-0077
Date Summary Prepared:	June 20, 2019
Trade Name:	FlexGard® Cut-Resistant Glove Liners
Common Name:	Surgical Glove Accessory, Glove Liners
Classification Name:	Surgeon's Glove (Accessory: Cut Resistant Glove Liners) 21 CFR 878.4460 Surgical Glove (Accessory), Class I Product Code: KGO Class I
Predicate Devices:	K160974 Gammex® Cut Resistant Glove Liner Ansell Healthcare Products LLC

Product Description

The FlexGard Cut Resistant Glove Liners provide an optional method of providing cut resistance to surgical gloves. The FlexGard Cut Resistant Glove Liners are applied between layers of surgical gloves. The FlexGard Cut Resistant Glove Liners are placed over a surgical glove and subsequently covered by a surgical glove.

The FlexGard Cut Resistant Glove Liners are ambidextrous, there is no left or right handed Glove Liner variations.

The FlexGard Cut Resistant Glove Liners are provided to the user terminally sterilized by a validated ethylene oxide process. The FlexGard Cut Resistant Glove Liners are labeled for single use.

The FlexGard Cut Resistant Glove Liners provide protection against cuts and slashes. The FlexGard Cut Resistant Glove Liners are not puncture resistant or cut proof.

Intended Use of the Device

The FlexGard Cut-Resistant Glove Liners are single use glove liners intended to help with protection against cuts when used with an inner and outer surgical glove. The Glove Liner must be worn between two surgical gloves.

Summary of Technological Characteristics

Technological Comparison Table			
Feature	**FlexGard® Cut-Resistant Glove Liners K190782**	**Gammex® Cut Resistant Glove Liner (Primary Predicate K160974)**	**Discussion of Feature Comparison**
Product Code, Classification	KGO 21 CFR 878.4460 Surgical Glove (Accessory), Class I	KGO 21 CFR 878.4460 Surgical Glove (Accessory), Class I	Identical
Indications for Use	The FlexGard® Cut-Resistant Glove Liners are single use glove liners intended to help with protection against cuts when used with an inner and outer surgical glove. The glove liner must be worn between two surgical gloves.	The Gammex(R) Cut Resistant Glove Liner is a single use glove liner intended to provide ANSI/ISEA 105 Cut Level Protection 2 against cuts when used with an inner and outer surgical glove. The glove liner should be worn between two surgical gloves.	Similar
Design	Knitted glove, ambidextrous	Knitted glove, ambidextrous	Similar
Cuff size feature	Color coded cuff band to reflect size	Color coded cuff band to reflect size	Similar
Material	High density polyethylene	High strength polyethylene	Similar
Cut Protection	ANSI / ISEA 105, Level 2 cut resistance tested to ASTM F1790-05.	ANSI Cut Level 2 tested to ASTM F1790-97	Same
Single use, disposable	Yes	Yes	Same
Provided sterile	Yes	Yes	Same
Sterilization method	Ethylene Oxide	Gamma Irradiation	Different
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}	Same
Sterile barrier package	Tyvek Pouch	Double Tyvek Pouch	Different
Shelf life	2 years	Unknown	Different
Biocompatibility evaluation	Cytotoxicity, Irritation, Sensitization	Cytotoxicity, Irritation, Sensitization	Same
Sizes	Six (6): Small (S)	Five (5): Extra Small (XS)	Similar

Technological Comparison Table			
Feature	**FlexGard® Cut-Resistant Glove Liners K190782**	**Gammex® Cut Resistant Glove Liner (Primary Predicate K160974)**	**Discussion of Feature Comparison**
	Medium (M) Large (L) Extra-Large (XL) Two-Extra-Large (2XL) Three-Extra-Large (3XL)	Small (S) Medium (M) Large (L) Extra Large (XL)	

Summary of Nonclinical Performance Test

Non-clinical testing was performed to demonstrate the subject device met the acceptance criteria of the standards used to evaluate the functionality of the device.

Test	**Test Method Summary**	**Acceptance Criteria**	**Result**
Cut Protection to ANSI/ISEA Level 2 cut resistance.	Cut protection of the FlexGard Cut Resistant Glove Liners has been demonstrated to ANSI/ISEA 105-2011, Level 2 by application of the ASTM F1790-05 test method after ethylene oxide sterilization, simulated distribution and two-year real time aging.	Meet requirements for ANSI/ISEA 105-2011, Level 2 cut resistance.	Pass
Sterility	FlexGard Cut Resistant Glove Liners are terminally ethylene oxide sterilized devices, by a validated EtO sterilization cycle, per ANSI/AAMI/ISO 11135-1: 2007.	Sterility assurance level (SAL) of 10^{-6}.	Pass
	The FlexGard Cut-Resistant Glove Liner sterile barrier package is a Tyvek pouch. The methods applied to evaluate the Tyvek pouch integrity post terminal sterilization by simulated distribution in compliance with ASTM 4169:2016, Tyvek pouch seal strength evaluated per ASTM F88/F88M-15, and Tyvek pouch integrity evaluated by ASTM F2096-11, Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Leak).	The sterile barrier Tyvek pouch must have a seal strength $\geq$ 1 lbf and not leak.	Pass
Biocompatibility	The following test methods were applied to final finished form FlexGard Cut Resistant Glove Liner, with passing results: • Cytotoxicity by ANSI/AAMI/ISO 10993-5:2009 (R)2014	Cytotoxicity passes for a Grade of ≤ 2.	Pass Grade = 1
	• Sensitization by ANSI/AAMI/ISO 10993-10:2010 (R)2014	Sensitization passes for a Grade = 0.	Pass Grade = 0
	• Irritation by ANSI/AAMI/ISO 10993-10:2010 (R)2014	Irritation passes for a Primary Irritation Index ≤ 0.4	Pass Primary Irritation Index = 0

Test	Test Method Summary	Acceptance Criteria	Result
Shelf life two (2) years (real time aging)	Shelf life testing of FlexGard Cut Resistant Glove Liners cut resistance to ANSI/ISEA 105-2011, Level 2 by application of the ASTM F1790-05 test method after two years of real time aging. Tyvek sterile barrier pouch integrity after two years of real time aging evaluated for seal strength per ASTM F88/F88M-15, and Tyvek pouch integrity evaluated by ASTM F2096-11, Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Leak).	Meet requirements for ANSI/ISEA 105-2011, Level 2 cut resistance. The sterile barrier Tyvek pouch must have a seal strength $\geq$ 1 lbf and not leak.	Pass

Clinical data is not needed for this submission.

Conclusion

The conclusions drawn from nonclinical tests demonstrate that the FlexGard Cut Resistant Glove Liners are as safe, as effective and performs well as or better than the legally marketed device Gammex® Cut Resistant Glove Liner, cleared to market by K160974.