

April 10, 2020

Molnlycke Health Care US LLC. Calen Souther Regulatory Affairs Specialist 5550 Peachtree Parkway, Suite 500 Norcross, Georgia 30092

Re: K193573

Trade/Device Name: Biogel® Skinsense® Indicator® Underglove tested for use with chemotherapy

agents, Biogel® PI UltraTouch® tested for use with chemotherapy agents, Biogel® PI Indicator® Underglove tested for use with chemotherapy agents, Biogel® PI tested for use with chemotherapy agents, Biogel® PI Micro tested for

use with chemotherapy agents

Regulation Number: 21 CFR 878.4460

Regulation Name: Non-Powdered Surgeon's Glove

Regulatory Class: Class I, reserved

Product Code: KGO, LZC Dated: January 16, 2020 Received: January 21, 2020

Dear Calen Souther:

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 <u>Federal Register</u>.

K193573 - Calen Souther Page 2

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-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">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,

CAPT 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

Indications for Use

510(k) Number (if known)

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020

Expiration Date: 06/30/2020 See PRA Statement below.

| K193573 |
|---|
| Device Name Biogel PI Indicator Underglove tested for use with chemotherapy agents |
| ndications for Use (Describe) |
| The Skinsense polyisoprene underglove is a disposable device made of polyisoprene that is intended to be worn on the nands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants. |
| In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs: |
| continued on next page] |
| |
| |
| |
| |
| |
| |
| Time of the (Colort and an both, as applicable) |
| 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

| Biogel® PI Indicator® Underglove | |
|----------------------------------|--------------------------------|
| Tested for use with ch | . , , |
| Drug and Concentration | Breakthrough detection time in |
| | minutes (0.01μg/cm²/mins) |
| Bleomycin 15 mg/ml | >240 |
| Busulfan 6 mg/ml | >240 |
| Carmustine 3.3 mg/ml | 17.3 |
| Cisplatin 1.0 mg/ml | >240 |
| Cyclophosphamide (Cytoxan) | >240 |
| 20 mg/ml | |
| Cytarabine 100 mg/ml | >240 |
| Dacarbazine (DTIC) 10 mg/ml | >240 |
| Doxorubicin Hydrochloride | >240 |
| 2 mg/ml | |
| Ellence 2 mg/ml | >240 |
| Etoposide (Toposar) 20 mg/ml | >240 |
| Fludarabine 25 mg/ml | >240 |
| Fluorouracil 50 mg/ml | >240 |
| Idarubicin 1 mg/ml | >240 |
| Ifosfamide 50 mg/ml | >240 |
| Mechlorethamine HCl 1 mg/ml | >240 |
| Melphalan 5 mg/ml | >240 |
| Methotrexate 25 mg/ml | >240 |
| Mitomycin C 0.5 mg/ml | >240 |
| Mitoxantrone 2 mg/ml | >240 |
| Paclitaxel (Taxol) 6 mg/ml | >240 |
| Paraplatin 10 mg/ml | >240 |
| Rituximab 10 mg/ml | >240 |
| Thiotepa 10 mg/ml | 24.1 |
| Vincristine Sulfate 1 mg/ml | >240 |

- Carmustine (BCNU) (3.3 mg/ml) has a minimum breakthrough time of 17.3 minutes.
- Thiotepa (10 mg/ml) has a minimum breakthrough time of 24.1 minutes

Indications for Use

510(k) Number (if known)

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020

Expiration Date: 06/30/2020 See PRA Statement below.

| K193573 | |
|--|---|
| Device Name Biogel PI Micro tested for use with chemotherapy agents | |
| Indications for Use (Describe) | |
| The Biogel PI Micro Surgical Glove is a disposable device made to be worn on the hands, usually in surgical settings, to provide a materials and other contaminants. | |
| In addition, these gloves were tested for use with chemotherapy of for Assessment of Resistance of Medical Gloves to Permeation by | |
| [continued on next page] | |
| | |
| | |
| | |
| | |
| | |
| | |
| 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 SEPARAT | TE 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

| Biogel® PI Micro | |
|------------------------------|--------------------------------|
| Tested for use with ch | , , <u> </u> |
| Drug and Concentration | Breakthrough detection time in |
| | minutes (0.01µg/cm²/mins) |
| Bleomycin 15 mg/ml | >240 |
| Busulfan 6 mg/ml | >240 |
| Carmustine 3.3 mg/ml | 10.0 |
| Cisplatin 1.0 mg/ml | >240 |
| Cyclophosphamide (Cytoxan) | >240 |
| 20 mg/ml | |
| Cytarabine 100 mg/ml | >240 |
| Dacarbazine (DTIC) 10 mg/ml | >240 |
| Doxorubicin Hydrochloride | >240 |
| 2 mg/ml | |
| Ellence 2 mg/ml | >240 |
| Etoposide (Toposar) 20 mg/ml | >240 |
| Fludarabine 25 mg/ml | >240 |
| Fluorouracil 50 mg/ml | >240 |
| Idarubicin 1 mg/ml | >240 |
| Ifosfamide 50 mg/ml | >240 |
| Mechlorethamine HCl 1 mg/ml | >240 |
| Melphalan 5 mg/ml | >240 |
| Methotrexate 25 mg/ml | >240 |
| Mitomycin C 0.5 mg/ml | >240 |
| Mitoxantrone 2 mg/ml | >240 |
| Paclitaxel (Taxol) 6 mg/ml | >240 |
| Paraplatin 10 mg/ml | >240 |
| Rituximab 10 mg/ml | >240 |
| Thiotepa 10 mg/ml | 20.3 |
| Vincristine Sulfate 1 mg/ml | >240 |

- Carmustine (BCNU) (3.3 mg/ml) has a minimum breakthrough time of 10.0 minutes.
- Thiotepa (10 mg/ml) has a minimum breakthrough time of 20.3 minutes

Indications for Use

510(k) Number (if known)

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020

Expiration Date: 06/30/2020 See PRA Statement below.

| K193573 |
|---|
| Device Name Biogel PI UltraTouch tested for use with chemotherapy agents |
| Indications for Use (Describe) |
| A powder-free sterile surgeon's 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 potentially infectious materials and other contaminants. |
| In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs: |
| [continued on next page] |
| |
| |
| |
| |
| |
| |
| 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

| Biogel® PI UltraTouch | |
|------------------------------|--------------------------------|
| Tested for use with ch | . , , |
| Drug and Concentration | Breakthrough detection time in |
| | minutes (0.01µg/cm²/mins) |
| Bleomycin 15 mg/ml | >240 |
| Busulfan 6 mg/ml | >240 |
| Carmustine 3.3 mg/ml | 24.2 |
| Cisplatin 1.0 mg/ml | >240 |
| Cyclophosphamide (Cytoxan) | >240 |
| 20 mg/ml | |
| Cytarabine 100 mg/ml | >240 |
| Dacarbazine (DTIC) 10 mg/ml | >240 |
| Doxorubicin Hydrochloride | >240 |
| 2 mg/ml | |
| Ellence 2 mg/ml | >240 |
| Etoposide (Toposar) 20 mg/ml | >240 |
| Fludarabine 25 mg/ml | >240 |
| Fluorouracil 50 mg/ml | >240 |
| Idarubicin 1 mg/ml | >240 |
| Ifosfamide 50 mg/ml | >240 |
| Mechlorethamine HCl 1 mg/ml | >240 |
| Melphalan 5 mg/ml | >240 |
| Methotrexate 25 mg/ml | >240 |
| Mitomycin C 0.5 mg/ml | >240 |
| Mitoxantrone 2 mg/ml | >240 |
| Paclitaxel (Taxol) 6 mg/ml | >240 |
| Paraplatin 10 mg/ml | >240 |
| Rituximab 10 mg/ml | >240 |
| Thiotepa 10 mg/ml | 17.9 |
| Vincristine Sulfate 1 mg/ml | >240 |

- Carmustine (BCNU) (3.3 mg/ml) has a minimum breakthrough time of 24.2 minutes.
- Thiotepa (10 mg/ml) has a minimum breakthrough time of 17.9 minutes

Indications for Use

510(k) Number (if known)

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2020 See PRA Statement below.

| K193573 | |
|--|---|
| Device Name Biogel PI tested for use with chemotherapy agents | |
| Indications for Use (Describe) | |
| A powder-free sterile surgeon's glove is a disposable device made of hands, usually in surgical settings, to provide a barrier against potent | |
| In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practic for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs: | |
| [continued on next page] | |
| | |
| | |
| | |
| | |
| | |
| | |
| 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) |

This section applies only to requirements of the Paperwork Reduction Act of 1995.

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

| Biogel® PI Tested for use with chemotherapy agents | |
|---|--|
| Drug and Concentration | Breakthrough detection time in minutes (0.01µg/cm²/mins) |
| Bleomycin 15 mg/ml | >240 |
| Busulfan 6 mg/ml | >240 |
| Carmustine 3.3 mg/ml | 26.7 |
| Cisplatin 1.0 mg/ml | >240 |
| Cyclophosphamide (Cytoxan) 20 mg/ml | >240 |
| Cytarabine 100 mg/ml | >240 |
| Dacarbazine (DTIC) 10 mg/ml | >240 |
| Doxorubicin Hydrochloride | >240 |
| 2 mg/ml | |
| Ellence 2 mg/ml | >240 |
| Etoposide (Toposar) 20 mg/ml | >240 |
| Fludarabine 25 mg/ml | >240 |
| Fluorouracil 50 mg/ml | >240 |
| Idarubicin 1 mg/ml | >240 |
| Ifosfamide 50 mg/ml | >240 |
| Mechlorethamine HCl 1 mg/ml | >240 |
| Melphalan 5 mg/ml | >240 |
| Methotrexate 25 mg/ml | >240 |
| Mitomycin C 0.5 mg/ml | >240 |
| Mitoxantrone 2 mg/ml | >240 |
| Paclitaxel (Taxol) 6 mg/ml | >240 |
| Paraplatin 10 mg/ml | >240 |
| Rituximab 10 mg/ml | >240 |
| Thiotepa 10 mg/ml | 28.7 |
| Vincristine Sulfate 1 mg/ml | >240 |

- Carmustine (BCNU) (3.3 mg/ml) has a minimum breakthrough time of 26.7 minutes.
- Thiotepa (10 mg/ml) has a minimum breakthrough time of 28.7 minutes

Indications for Use

510(k) Number (if known)

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020

Expiration Date: 06/30/2020 See PRA Statement below.

| K193573 | |
|---|--|
| Device Name Biogel Skinsense Indicator Underglove tested for use with chemotherapy agents | |
| Indications for Use (Describe) A powder-free, sterile, surgeon's glove is a disposable device made of non-latex that is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants. | |
| In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs: | |
| [continued on next page] | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| Type of Use (Select one or both, as applicable) | |
| Prescription Use (Part 21 CFR 801 Subpart D) | |
| 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

| Biogel® Skinsense® Indicator® Underglove | |
|--|--------------------------------|
| Tested for use with ch | ., 0 |
| Drug and Concentration | Breakthrough detection time in |
| | minutes (0.01µg/cm²/mins) |
| Bleomycin 15 mg/ml | >240 |
| Busulfan 6 mg/ml | >240 |
| Carmustine 3.3 mg/ml | 6.6 |
| Cisplatin 1.0 mg/ml | >240 |
| Cyclophosphamide (Cytoxan) | >240 |
| 20 mg/ml | |
| Cytarabine 100 mg/ml | >240 |
| Dacarbazine (DTIC) 10 mg/ml | >240 |
| Doxorubicin Hydrochloride | >240 |
| 2 mg/ml | |
| Ellence 2 mg/ml | >240 |
| Etoposide (Toposar) 20 mg/ml | >240 |
| Fludarabine 25 mg/ml | >240 |
| Fluorouracil 50 mg/ml | >240 |
| Idarubicin 1 mg/ml | >240 |
| Ifosfamide 50 mg/ml | >240 |
| Mechlorethamine HCl 1 mg/ml | >240 |
| Melphalan 5 mg/ml | >240 |
| Methotrexate 25 mg/ml | >240 |
| Mitomycin C 0.5 mg/ml | >240 |
| Mitoxantrone 2 mg/ml | >240 |
| Paclitaxel (Taxol) 6 mg/ml | >240 |
| Paraplatin 10 mg/ml | >240 |
| Rituximab 10 mg/ml | >240 |
| Thiotepa 10 mg/ml | 16.9 |
| Vincristine Sulfate 1 mg/ml | >240 |

- Carmustine (BCNU) (3.3 mg/ml) has a minimum breakthrough time of 6.6 minutes.
- Thiotepa (10 mg/ml) has a minimum breakthrough time of 16.9 minutes

510(k) Summary

The information contained herein is being provided in accordance with the requirements of 21 CFR 807.92(c).

Date Prepared:

Applicant: Mölnlycke Health Care US, LLC.

5550 Peachtree Parkway, Suite 500

Norcross, GA 30092

March 23, 2020

Registration Number: 3004763499 Owner/Operator Number: 8030877

Official Correspondent: Calen Souther

Regulatory Affairs Specialist Phone: 770-595-4222 Fax: 678-245-7746

Email: calen.souther@molnlycke.com

Trade/Proprietary Names: Biogel® Skinsense® Indicator® Underglove tested for use with

chemotherapy agents

Biogel® PI UltraTouch® tested for use with chemotherapy

agents

Biogel® PI Indicator® Underglove tested for use with

chemotherapy agents

Biogel® PI tested for use with chemotherapy agents

Biogel® PI Micro tested for use with chemotherapy agents

Common Name: Surgeon's Gloves

Regulation Name: Non-powdered surgeon's gloves

Device Class I

Regulation Number: 21 CFR 878.4460

Product Code: KGO, LZC

Predicate Device Information: K140477

Biogel® PI UltraTouch® G Surgical Glove tested for use with

chemotherapy agents

Biogel® Skinsense® Surgical Glove tested for use with

chemotherapy agents

Reason for 510(k) submission

The purpose of this Traditional 510(k) submission is to add a "Tested for use with chemotherapy agents" claim to the following existing, 510(k) cleared surgical gloves: Biogel® Skinsense® Underglove, Biogel® PI UltraTouch®, Biogel® PI Indicator® Underglove, Biogel® PI, Biogel® PI Micro.

Description of Devices

The Biogel® surgical gloves that are the subject of this submission are sterile, single-use, powder-free gloves that are constructed of either synthetic polyisoprene or synthetic polychloroprene. Refer to **Tables 6-1 to 6-5** for a detailed description of the technological characteristics and comparison to the applicable predicate device.

Indications for Use

Biogel® Skinsense® Indicator® Underglove tested for use with chemotherapy agents

A powder-free, sterile, surgeon's glove is a disposable device made of non-latex that is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants.

| Drug and Concentration | Breakthrough |
|------------------------|--------------------------------|
| | detection time in |
| | minutes |
| | (0.01µg/cm ² /mins) |
| Bleomycin 15 mg/ml | >240 |
| Busulfan 6 mg/ml | >240 |
| Carmustine 3.3 mg/ml | 6.6 |
| Cisplatin 1.0 mg/ml | >240 |
| Cyclophosphamide | >240 |
| (Cytoxan) | |
| 20 mg/ml | |
| Cytarabine 100 mg/ml | >240 |
| Dacarbazine (DTIC) 10 | >240 |
| mg/ml | |
| Doxorubicin | >240 |
| Hydrochloride | |
| 2 mg/ml | |
| Ellence 2 mg/ml | >240 |
| Etoposide (Toposar) 20 | >240 |
| mg/ml | |
| Fludarabine 25 mg/ml | >240 |
| Fluorouracil 50 mg/ml | >240 |
| Idarubicin 1 mg/ml | >240 |
| Ifosfamide 50 mg/ml | >240 |
| Mechlorethamine HCl 1 | >240 |
| mg/ml | |
| Melphalan 5 mg/ml | >240 |
| Methotrexate 25 mg/ml | >240 |

| Mitomycin C 0.5 mg/ml | >240 |
|-----------------------|------|
| Mitoxantrone 2 mg/ml | >240 |
| Paclitaxel (Taxol) 6 | >240 |
| mg/ml | |
| Paraplatin 10 mg/ml | >240 |
| Rituximab 10 mg/ml | >240 |
| Thiotepa 10 mg/ml | 16.9 |
| Vincristine Sulfate 1 | >240 |
| mg/ml | |

- Carmustine (3.3 mg/ml) has a minimum breakthrough time of 6.6 minutes.
- Thiotepa (10 mg/ml) has a minimum breakthrough time of 16.9 minutes

Biogel® PI Micro tested for use with chemotherapy agents

The Biogel PI Micro Surgical Glove is a disposable device made of polyisoprene material that is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants.

| Breakthrough |
|--------------------------------|
| detection time in |
| minutes |
| (0.01μg/cm ² /mins) |
| >240 |
| >240 |
| 10.0 |
| >240 |
| >240 |
| |
| |
| >240 |
| >240 |
| |
| >240 |
| |
| |
| >240 |
| >240 |
| |
| >240 |
| >240 |
| >240 |
| >240 |
| >240 |
| |
| >240 |
| >240 |
| |

| Mitomycin C 0.5 mg/ml | >240 |
|-----------------------|------|
| Mitoxantrone 2 mg/ml | >240 |
| Paclitaxel (Taxol) 6 | >240 |
| mg/ml | |
| Paraplatin 10 mg/ml | >240 |
| Rituximab 10 mg/ml | >240 |
| Thiotepa 10 mg/ml | 20.3 |
| Vincristine Sulfate 1 | >240 |
| mg/ml | |

- Carmustine (3.3 mg/ml) has a minimum breakthrough time of 10.0 minutes.
- Thiotepa (10 mg/ml) has a minimum breakthrough time of 20.3 minutes

Biogel® PI UltraTouch® tested for use with chemotherapy agents

A powder-free sterile surgeon's 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 potentially infectious materials and other contaminants.

| Drug and Concentration | Breakthrough |
|------------------------|--------------------------------|
| | detection time in |
| | minutes |
| | (0.01µg/cm ² /mins) |
| Bleomycin 15 mg/ml | >240 |
| Busulfan 6 mg/ml | >240 |
| Carmustine 3.3 mg/ml | 24.2 |
| Cisplatin 1.0 mg/ml | >240 |
| Cyclophosphamide | >240 |
| (Cytoxan) | |
| 20 mg/ml | |
| Cytarabine 100 mg/ml | >240 |
| Dacarbazine (DTIC) 10 | >240 |
| mg/ml | |
| Doxorubicin | >240 |
| Hydrochloride | |
| 2 mg/ml | |
| Ellence 2 mg/ml | >240 |
| Etoposide (Toposar) 20 | >240 |
| mg/ml | |
| Fludarabine 25 mg/ml | >240 |
| Fluorouracil 50 mg/ml | >240 |
| Idarubicin 1 mg/ml | >240 |
| Ifosfamide 50 mg/ml | >240 |
| Mechlorethamine HCl 1 | >240 |
| mg/ml | |
| Melphalan 5 mg/ml | >240 |
| Methotrexate 25 mg/ml | >240 |
| | |

| Mitomycin C 0.5 mg/ml | >240 |
|-----------------------|------|
| Mitoxantrone 2 mg/ml | >240 |
| Paclitaxel (Taxol) 6 | >240 |
| mg/ml | |
| Paraplatin 10 mg/ml | >240 |
| Rituximab 10 mg/ml | >240 |
| Thiotepa 10 mg/ml | 17.9 |
| Vincristine Sulfate 1 | >240 |
| mg/ml | |

- Carmustine (BCNU) (3.3 mg/ml) has a minimum breakthrough time of 24.2 minutes.
- Thiotepa (10 mg/ml) has a minimum breakthrough time of 17.9 minutes

Biogel® PI tested for use with chemotherapy agents

A powder-free sterile surgeon's 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 potentially infectious materials and other contaminants.

| Breakthrough |
|--------------------------------|
| detection time in |
| minutes |
| (0.01µg/cm ² /mins) |
| >240 |
| >240 |
| 26.7 |
| >240 |
| >240 |
| |
| |
| >240 |
| >240 |
| |
| >240 |
| |
| |
| >240 |
| >240 |
| |
| >240 |
| >240 |
| >240 |
| >240 |
| >240 |
| |
| >240 |
| >240 |
| |

| Mitomycin C 0.5 mg/ml | >240 |
|-----------------------|------|
| Mitoxantrone 2 mg/ml | >240 |
| Paclitaxel (Taxol) 6 | >240 |
| mg/ml | |
| Paraplatin 10 mg/ml | >240 |
| Rituximab 10 mg/ml | >240 |
| Thiotepa 10 mg/ml | 28.7 |
| Vincristine Sulfate 1 | >240 |
| mg/ml | |

- Carmustine (BCNU) (3.3 mg/ml) has a minimum breakthrough time of 26.7 minutes.
- Thiotepa (10 mg/ml) has a minimum breakthrough time of 28.7 minutes

Biogel® PI Indicator® Underglove tested for use with chemotherapy agents

The Skinsense polyisoprene underglove 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 potentially infectious materials and other contaminants.

| Drug and Concentration | Breakthrough |
|------------------------|--------------------------------|
| | detection time in |
| | minutes |
| | (0.01µg/cm ² /mins) |
| Bleomycin 15 mg/ml | >240 |
| Busulfan 6 mg/ml | >240 |
| Carmustine 3.3 mg/ml | 17.3 |
| Cisplatin 1.0 mg/ml | >240 |
| Cyclophosphamide | >240 |
| (Cytoxan) | |
| 20 mg/ml | |
| Cytarabine 100 mg/ml | >240 |
| Dacarbazine (DTIC) 10 | >240 |
| mg/ml | |
| Doxorubicin | >240 |
| Hydrochloride | |
| 2 mg/ml | |
| Ellence 2 mg/ml | >240 |
| Etoposide (Toposar) 20 | >240 |
| mg/ml | |
| Fludarabine 25 mg/ml | >240 |
| Fluorouracil 50 mg/ml | >240 |
| Idarubicin 1 mg/ml | >240 |
| Ifosfamide 50 mg/ml | >240 |
| Mechlorethamine HCl 1 | >240 |
| mg/ml | |
| Melphalan 5 mg/ml | >240 |
| Methotrexate 25 mg/ml | >240 |
| | |

| Mitomycin C 0.5 mg/ml | >240 |
|-----------------------|------|
| Mitoxantrone 2 mg/ml | >240 |
| Paclitaxel (Taxol) 6 | >240 |
| mg/ml | |
| Paraplatin 10 mg/ml | >240 |
| Rituximab 10 mg/ml | >240 |
| Thiotepa 10 mg/ml | 24.1 |
| Vincristine Sulfate 1 | >240 |
| mg/ml | |

- Carmustine (BCNU) (3.3 mg/ml) has a minimum breakthrough time of 17.3 minutes.
- Thiotepa (10 mg/ml) has a minimum breakthrough time of 24.1 minutes

Table 6-1: Technological Characteristics Comparison

| | Subject Device Predicate Device | | | | | | |
|------------------|---|------------------------------|------------------------|-----------------------------|--|------------------------|--|
| Feature | Biogel® Skinsense® Indic | ator® Underglove test | ed for | Biogel® Skinsense® Surgi | e with | | |
| | use with chemotherapy agents | | | chemotherapy agents | | | |
| 510(k) clearance | Originally cleared under I | (053102; subject of th | is | K140477 | | | |
| | premarket notification to | add "tested for use w | ith | | | | |
| | chemotherapy agents" cl | aim | | | | | |
| Manufacturer | Mölnlycke Health Care | | | Mölnlycke Health Care | | | |
| Regulation | 21 CFR 878.4460, | | | 21 CFR 878.4460, | | | |
| Class Name | Surgeon's Gloves | | | Surgeon's Gloves | | | |
| Classification | Class I | | | Class I | | | |
| Product Code | KGO, LZC | | | KGO, LZC | | | |
| Indication for | A powder-free, sterile, s | surgeon's glove is a c | disposable | Biogel® Skinsense® Surgi | cal Gloves are intende | ed to be worn on the | |
| Use | device made of non-latex that is intended to be worn on | | hands, usually in surg | ical settings, to pro | vide barrier against | | |
| | the hands, usually in surg | ical settings, to provide | e a barrier | potentially infectious ma | terial and other contar | | |
| | against potentially info | ectious materials ai | nd other | | | | |
| | contaminants. | | | In addition, these gloves w | were tested for use with | n chemotherapy drugs | |
| | | | | in accordance with ASTM | D6978 Standard Pract | tice for Assessment of | |
| | In addition, these glov | es were tested for | use with | Medical Gloves to Perme | ation by Chemotherap | y Drugs: | |
| | chemotherapy drugs in | accordance with AST | M D6978 | | | | |
| | Standard Practice for | Assessment of Resis | stance of | Drug and Concentration | Breakthrough | | |
| | Medical Gloves to Perme | ation by Chemotherap | y Drugs: | | detection time in | | |
| | - | 1 | 7 | | minutes | | |
| | Drug and Concentration | Breakthrough | | Bleomycin 15 mg/ml | (0.01μg/cm ² /mins) >240 | | |
| | | detection time in | | Busulfan 6 mg/ml | >240 | | |
| | | minutes (0.01µg/cm²/mins) | | Carmustine 3.3 mg/ml | 60.2 | | |
| | Bleomycin 15 mg/ml | (0.01μg/cm /mms) >240 | | Cisplatin 1.0 mg/ml | >240 | | |
| | Busulfan 6 mg/ml | >240 | | Cyclophosphamide | >240 | | |
| | Carmustine 3.3 mg/ml | 6.6 | | (Cytoxan) | | | |
| | Cisplatin 1.0 mg/ml | >240 | 1 | 20 mgl/ml | | | |
| | Cyclophosphamide | >240 | | Cytarabine 100 mg/ml | >240 | | |
| | (Cytoxan) | | | Dacarbazine (DTIC) 10 | >240 | | |
| | 20 mg/ml | | | mg/ml | | | |
| | Cytarabine 100 mg/ml | >240 | | | | | |

| | Dacarbazine (DTIC) 10 | >240 | Doxorubicin | >240 | |
|----------|---|--------------------------------|--|------------------------|-------------------|
| | mg/ml | | Hydrochloride | | |
| | Doxorubicin | >240 | 2 mg/ml | | |
| | Hydrochloride | | Ellence 2 mg/ml | >240 | |
| | 2 mg/ml | | Etoposide (Toposar) 20 | >240 | |
| | Ellence 2 mg/ml | >240 | mg/ml | | |
| | Etoposide (Toposar) 20 | >240 | Fludarabine 25 mg/ml | >240 | |
| | mg/ml | | Fluorouracil 50 mg/ml | >240 | |
| | Fludarabine 25 mg/ml | >240 | Idarubicin 1 mg/ml | >240 | |
| | Fluorouracil 50 mg/ml | >240 | Ifosfamide 50 mg/ml | >240 | |
| | Idarubicin 1 mg/ml | >240 | Mechlorethamine HCl 1 | >240 | |
| | Ifosfamide 50 mg/ml | >240 | mg/ml | | |
| | Mechlorethamine HCl 1 | >240 | Melphalan 5 mg/ml | >240 | |
| | mg/ml | | Methotrexate 25 mg/ml | >240 | |
| | Melphalan 5 mg/ml | >240 | Mitomycin C 0.5 mg/ml | >240 | |
| | Methotrexate 25 mg/ml | >240 | Mitoxantrone 2 mg/ml | >240 | |
| | Mitomycin C 0.5 mg/ml | >240 | Paclitaxel (Taxol) 6 | >240 | |
| | Mitoxantrone 2 mg/ml | >240 | mg/ml | | |
| | Paclitaxel (Taxol) 6 | >240 | Paraplatin 10 mg/ml | >240 | |
| | mg/ml | | Rituximab 10 mg/ml | >240 | |
| | Paraplatin 10 mg/ml | >240 | Thiotepa 10 mg/ml | 75.8 | |
| | Rituximab 10 mg/ml | >240 | Trisenox 0.1 mg/ml | >240 | |
| | Thiotepa 10 mg/ml | 16.9 | Vincristine Sulfate 1 | >240 | |
| | Vincristine Sulfate 1 | >240 | mg/ml | | |
| | mg/ml | | | | |
| | | | Please note that Carmustine (| 3.3 mg/ml) and Thioteg | a (10 mg/ml) have |
| | Please note that Carmustine (3 | 3.3 mg/ml) and Thiotepa (10 | much lower permeation times | | |
| | | neation times compared to othe | r | · | ., - |
| | chemotherapy drugs: | · | Carmustine (BCNU) | (3.3 mg/ml) has a mini | mum breakthrough |
| | | | time of 60.2 minutes. Thiotepa (10 mg/ml) has a minimum breakthrough time of 75.8 | | |
| | | (3.3 mg/ml) has a minimum | | | |
| | breakthrough time o | | minutes | | |
| | ■ Thiotepa (10 mg/m time of 16.9 minute | l) has a minimum breakthroug | n | | |
| Design | Single-use | 5 | Single-use | | |
| = 55.6 | Sterile | | Sterile | | |
| | Powder-free | | Powder-free | | |
| | | | | | |
| | Hand specific | | Hand specific | | |
| | Beaded cuff | | Beaded cuff | | |
| Material | Synthetic Polychloroprene | | Synthetic Polychloroprene | | |

| Sterilization | Irradiation | Irradiation |
|-----------------|--|--|
| Method | | |
| Sterility (SAL) | 10 ⁻⁶ | 10 ⁻⁶ |
| Color | Blue | Straw (Natural) |
| Shelf Life | 3-years | 3-years |
| Resistance to | Meets ASTM D6978-05 (2019) | Meets ASTM D6978-05 (2019) |
| Permeation by | | |
| Chemotherapy | | |
| Drugs | | |
| Freedom from | AQL meets 21 CFR 800.20 and ASTM D3577-09 (2015) | AQL meets 21 CFR 800.20 and ASTM D3577-09 (2015) requirements |
| Holes | requirements | |
| Powder Residue | Meets requirements of ≤ 2.0 mg/glove for Powder-free | Meets requirements of ≤ 2.0 mg/glove for Powder-free designation |
| | designation per ASTM D3577-09 (2015) | per ASTM D3577-09 (2015) |
| Dimensions and | Meets ASTM D3577-09 (2015) | Meets ASTM D3577-09 (2015) |
| Physical | | |
| Properties | | |

Table 6-2: Technological Characteristics Comparison

| | Subject Device | | | Subject Device Predicate Device | | | |
|--------------------|---|---|--|---|--------------------------------|-----------------|--|
| Feature | Biogel® PI Micro tested for use with chemotherapy agents | | Biogel® PI Micro tested for use with chemotherapy agents Biogel® PI UltraTouch® G Surgical Glove tested for | | I for use with | | |
| | | | | chemotherapy agents | | | |
| 510(k) clearance | Originally cleared under K141719; subject of this premarket | | | K140477 | | | |
| | notification to add "teste | d for use with chemot | herapy | | | | |
| | agents" claim | | | | | | |
| Manufacturer | Mölnlycke Health Care | | | Mölnlycke Health Care | | | |
| Regulation | 21 CFR 878.4460, 21 CFR | 878.6250 | | 21 CFR 878.4460, 21 CFR | 878.6250 | | |
| Class Name | Surgeon's Gloves | | | Surgeon's Gloves | | | |
| Classification | Class I | | | Class I | | | |
| Product Code | KGO, LZC | | | KGO, LZC | | | |
| Indication for Use | The Biogel PI Micro Surgio | al Glove is a disposabl | le device made | Biogel® PI UltraTouch® (| G Surgical Gloves are | intended to be | |
| | of polyisoprene material | • | | worn on the hands, usual | • | | |
| | hands, usually in surgical | | | against potentially infecti | | • | |
| | potentially infectious mat | | _ | .0 | | | |
| | , | | | In addition, these gloves were tested for use with chemotherapy | | th chemotherapy | |
| | In addition, these gloves were tested for use with | | | drugs in accordance with ASTM D6978 Standard Practice for | | | |
| | chemotherapy drugs in a | | | Assessment of Medical Gloves to Permeation by Chemotherapy | | | |
| | | Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs: | | Drugs: | | , , , , | |
| | | | | | | | |
| | Drug and Concentration | | | Drug and Concentration | Breakthrough |] | |
| | | detection time in | | | detection time in | | |
| | | minutes | | | minutes | | |
| | | (0.01μg/cm ² /mins) | | | (0.01μg/cm ² /mins) | | |
| | Bleomycin 15 mg/ml | >240 | | Bleomycin 15 mg/ml | >240 | | |
| | Busulfan 6 mg/ml | >240 | _ | Busulfan 6 mg/ml | >240 | - | |
| | Carmustine 3.3 mg/ml | 10.0 | | Carmustine 3.3 mg/ml | 12.1 | - | |
| | Cisplatin 1.0 mg/ml | >240 | - | Cisplatin 1.0 mg/ml | >240 | | |
| | Cyclophosphamide | >240 | | Cyclophosphamide | >240 | | |
| | (Cytoxan) 20 mg/ml | | | (Cytoxan) 20 mgl/ml | | | |
| | Cytarabine 100 mg/ml | >240 | - | Cytarabine 100 mg/ml | >240 | - | |
| | Dacarbazine (DTIC) 10 | >240 | 1 | Dacarbazine (DTIC) 10 | >240 | - | |
| | mg/ml | , 210 | | mg/ml | , 210 | | |
| | Doxorubicin | >240 | 1 | Doxorubicin | >240 | 1 | |
| | Hydrochloride | | | Hydrochloride | | | |
| | 2 mg/ml | | | 2 mg/ml | |] | |

| | Ellence 2 mg/ml | >240 | | Ellence 2 mg/ml | >240 | |
|-----------------|--------------------------------------|---|------|---|--|-----------------|
| | Etoposide (Toposar) 20 | >240 | | Etoposide (Toposar) 20 | >240 | |
| | mg/ml | <i>></i> 240 | | mg/ml | <i>7</i> 240 | |
| | Fludarabine 25 mg/ml | >240 | = | Fludarabine 25 mg/ml | >240 | |
| | Fluorouracil 50 mg/ml | >240 | 1 | Fluorouracil 50 mg/ml | >240 | |
| | Idarubicin 1 mg/ml | >240 | | Idarubicin 1 mg/ml | >240 | |
| | Ifosfamide 50 mg/ml | >240 | | Ifosfamide 50 mg/ml | >240 | |
| | Mechlorethamine HCl 1 | >240 | | Mechlorethamine HCl 1 | >240 | |
| | mg/ml | | | mg/ml | | |
| | Melphalan 5 mg/ml | >240 | | Melphalan 5 mg/ml | >240 | |
| | Methotrexate 25 mg/ml | >240 | _ | Methotrexate 25 mg/ml | >240 | |
| | Mitomycin C 0.5 mg/ml | >240 | | Mitomycin C 0.5 mg/ml | >240 | |
| | Mitoxantrone 2 mg/ml | >240 | | Mitoxantrone 2 mg/ml | >240 | |
| | Paclitaxel (Taxol) 6 | >240 | | Paclitaxel (Taxol) 6 | >240 | |
| | mg/ml | | | mg/ml | | |
| | Paraplatin 10 mg/ml | >240 | | Paraplatin 10 mg/ml | >240 | |
| | Rituximab 10 mg/ml | >240 | | Rituximab 10 mg/ml | >240 | |
| | Thiotepa 10 mg/ml | 20.3 | = | Thiotepa 10 mg/ml | 15.5 | |
| | Vincristine Sulfate 1 | >240 | | Trisenox 0.1 mg/ml | >240 | |
| | mg/ml | | | Vincristine Sulfate 1 mg/ml | >240 | |
| | breakthrough time Thiotepa (10 mg/ml | times compared to oth (3.3 mg/ml) has a min | imum | Please note that Carmustine (a have much lower permeation drugs: Carmustine (BCNU) breakthrough time | times compared to oth (3.3 mg/ml) has a mini of 12.1 minutes. | er chemotherapy |
| | of 20.3 minutes | | | 15.5 minutes |) has a minimum break | through time of |
| Design | Single-use | | | Single-use | | |
| | Sterile | | | Sterile | | |
| | Powder-free | | | Powder-free | | |
| | Hand specific | | | Hand specific | | |
| | Beaded cuff | | | Beaded cuff | | |
| Material | Synthetic Polyisoprene | | | Synthetic Polyisoprene | | |
| Sterilization | Irradiation | | | Irradiation | | |
| Method | | | | | | |
| Sterility (SAL) | 10 ⁻⁶ | | | 10 ⁻⁶ | | |
| , , , | | | | | | |

| Color | Straw (Natural) | Straw (Natural) |
|----------------|--|--|
| Shelf Life | 3-years | 3-years |
| Resistance to | Meets ASTM D6978-05 (2019) | Meets ASTM D6978-05 |
| Permeation by | | |
| Chemotherapy | | |
| Drugs | | |
| Freedom from | AQL meets 21 CFR 800.20 and ASTM D3577-09 (2015) | AQL meets 21 CFR 800.20 and ASTM D3577-09 (2015) |
| Holes | requirements | requirements |
| Powder Residue | Meets requirements of ≤ 2.0 mg/glove for Powder-free | Meets requirements of ≤ 2.0 mg/glove for Powder-free |
| | designation per ASTM D3577-09 (2015) | designation per ASTM D3577-09 (2015) |
| Dimensions and | Meets ASTM D3577-09 (2015) | Meets ASTM D3577-09 (2015) |
| Physical | | |
| Properties | | |

Table 6-3: Technological Characteristics Comparison

| | Subject Device | | | Predicate | | |
|--------------------|----------------------------|--|-----------------|---|---------------------------|-------------------|
| Feature | Biogel® PI UltraTouch® to | ested for use with che | motherapy | Biogel® PI UltraTouch® G Surgical Glove tested for use with | | for use with |
| | agents | | | chemotherapy agents | | |
| 510(k) clearance | Previously cleared under | K050184; subject of th | nis premarket | K140477 | | |
| | notification to add "teste | d for use with chemot | herapy | | | |
| | agents" claim | | | | | |
| Manufacturer | Mölnlycke Health Care | | | Mölnlycke Health Care | | |
| Regulation | 21 CFR 878.4460, 21 CFR | 878.6250 | | 21 CFR 878.4460, 21 CFR | 878.6250 | |
| Class Name | Surgeon's Gloves | | | Surgeon's Gloves | | |
| Classification | Class I | | | Class I | | |
| Product Code | KGO, LZC | | | KGO, LZC | | |
| Indication for Use | A powder-free sterile sur | rgeon's glove is a disp | oosable device | Biogel® PI UltraTouch® (| G Surgical Gloves are | intended to be |
| | made of polyisoprene th | nat is intended to be | worn on the | worn on the hands, usual | y in surgical settings, t | o provide barrier |
| | hands, usually in surgical | settings, to provide a | barrier against | against potentially infecti | ous material and othe | r contaminants. |
| | potentially infectious mat | terials and other conta | aminants. | | | |
| | | | | In addition, these gloves were tested for use with chemotherapy | | th chemotherapy |
| | In addition, these glo | oves were tested f | for use with | drugs in accordance with ASTM D6978 Standard Practice for | | lard Practice for |
| | chemotherapy drugs ir | n accordance with | ASTM D6978 | | | y Chemotherapy |
| | Standard Practice for As | sessment of Resistan | ice of Medical | Drugs: | | |
| | Gloves to Permeation by | Chemotherapy Drugs: | _ | | | - |
| | Drug and Concentration | Breakthrough | | Drug and Concentration | Breakthrough | |
| | | detection time in | | | detection time in | |
| | | minutes | | | minutes | |
| | Bleomycin 15 mg/ml | (0.01μg/cm ² /mins) >240 | 1 | Bleomycin 15 mg/ml | (0.01μg/cm²/mins) >240 | - |
| | Busulfan 6 mg/ml | >240 | - | Busulfan 6 mg/ml | >240 | - |
| | Carmustine 3.3 mg/ml | 24.2 | 1 | Carmustine 3.3 mg/ml | 12.1 | |
| | Cisplatin 1.0 mg/ml | >240 | | Cisplatin 1.0 mg/ml | >240 | |
| | Cyclophosphamide | >240 | 1 | Cyclophosphamide | >240 | 1 |
| | (Cytoxan) | | | (Cytoxan) | | |
| | 20 mg/ml | | | 20 mgl/ml | | |
| | Cytarabine 100 mg/ml | >240 | _ | Cytarabine 100 mg/ml | >240 | |
| | Dacarbazine (DTIC) 10 | >240 | | Dacarbazine (DTIC) 10 | >240 | |
| | mg/ml Doxorubicin | >240 | - | mg/ml Doxorubicin | .240 | |
| | Hydrochloride | >240 | | Hydrochloride | >240 | |
| | 1 1 ' | | | | | |
| | 2 mg/ml | | | 2 mg/ml | | |

| | Ellence 2 mg/ml | >240 | | Ellence 2 mg/ml | >240 | |
|-----------------|--|-----------------------|----------|--|-------------------------|-----------------|
| | Etoposide (Toposar) 20 | >240 | - | Etoposide (Toposar) 20 | >240 | |
| | mg/ml | 12.0 | | mg/ml | 12.0 | |
| | Fludarabine 25 mg/ml | >240 | | Fludarabine 25 mg/ml | >240 | |
| | Fluorouracil 50 mg/ml | >240 | | Fluorouracil 50 mg/ml | >240 | |
| | Idarubicin 1 mg/ml | >240 | 1 | Idarubicin 1 mg/ml | >240 | |
| | Ifosfamide 50 mg/ml | >240 | | Ifosfamide 50 mg/ml | >240 | |
| | Mechlorethamine HCl 1 | >240 | | Mechlorethamine HCl 1 | >240 | |
| | mg/ml | | | mg/ml | | |
| | Melphalan 5 mg/ml | >240 | | Melphalan 5 mg/ml | >240 | |
| | Methotrexate 25 mg/ml | >240 | | Methotrexate 25 mg/ml | >240 | |
| | Mitomycin C 0.5 mg/ml | >240 | | Mitomycin C 0.5 mg/ml | >240 | |
| | Mitoxantrone 2 mg/ml | >240 | | Mitoxantrone 2 mg/ml | >240 | |
| | Paclitaxel (Taxol) 6 | >240 | | Paclitaxel (Taxol) 6 | >240 | |
| | mg/ml | | | mg/ml | | |
| | Paraplatin 10 mg/ml | >240 | | Paraplatin 10 mg/ml | >240 | |
| | Rituximab 10 mg/ml | >240 | | Rituximab 10 mg/ml | >240 | |
| | Thiotepa 10 mg/ml | 17.9 | <u> </u> | Thiotepa 10 mg/ml | 15.5 | |
| | Vincristine Sulfate 1 | >240 | | Trisenox 0.1 mg/ml | >240 | |
| | mg/ml | | | Vincristine Sulfate 1 | >240 | |
| | breakthrough time | times compared to oth | imum | breakthrough time | n times compared to oth | er chemotherapy |
| Design | Single-use Sterile Powder-free Hand specific Beaded cuff | | | Single-use Sterile Powder-free Hand specific Beaded cuff | | |
| Material | Synthetic Polyisoprene | | | Synthetic Polyisoprene | | |
| Sterilization | Irradiation | | | Irradiation | | |
| Method | | | | | | |
| Sterility (SAL) | 10 ⁻⁶ | | | 10 ⁻⁶ | | |
| , , , | | | | <u> </u> | | |

| Color | Straw (Natural) | Straw (Natural) |
|----------------|--|--|
| Shelf Life | 3-years | 3-years |
| Resistance to | Meets ASTM D6978-05 (2019) | Meets ASTM D6978-05 |
| Permeation by | | |
| Chemotherapy | | |
| Drugs | | |
| Freedom from | AQL meets 21 CFR 800.20 and ASTM D3577-09 (2015) | AQL meets 21 CFR 800.20 and ASTM D3577-09 (2015) |
| Holes | requirements | requirements |
| Powder Residue | Meets requirements of ≤ 2.0 mg/glove for Powder-free | Meets requirements of ≤ 2.0 mg/glove for Powder-free |
| | designation per ASTM D3577-09 (2015) | designation per ASTM D3577-09 (2015) |
| Dimensions and | Meets ASTM D3577-09 (2015) | Meets ASTM D3577-09 (2015) |
| Physical | | |
| Properties | | |

Table 6-4: Technological Characteristics Comparison

| | Subject Device | | | Predicate Device | | |
|--------------------|-------------------------------------|-------------------------|-----------------|---|---------------------------|-------------------|
| Feature | Biogel® PI tested for use | with chemotherapy a | gents | Biogel® PI UltraTouch® G | Surgical Glove tested | for use with |
| | | | | chemotherapy agents | | |
| 510(k) clearance | Previously cleared under | K050184/K053442; su | bject of this | K140477 | | |
| | premarket notification to | add "tested for use w | rith | | | |
| | chemotherapy agents" cl | aim | | | | |
| Manufacturer | Mölnlycke Health Care | | | Mölnlycke Health Care | | |
| Regulation | 21 CFR 878.4460, 21 CFR | 878.6250 | | 21 CFR 878.4460, 21 CFR | 878.6250 | |
| Class Name | Surgeon's Gloves | | | Surgeon's Gloves | | |
| Classification | Class I | | | Class I | | |
| Product Code | KGO, LZC | | | KGO, LZC | | |
| Indication for Use | A powder-free sterile sur | rgeon's glove is a disp | osable device | Biogel® PI UltraTouch® (| G Surgical Gloves are | intended to be |
| | made of polyisoprene th | nat is intended to be | worn on the | worn on the hands, usual | y in surgical settings, t | o provide barrier |
| | hands, usually in surgical | settings, to provide a | barrier against | against potentially infecti | ous material and othe | r contaminants. |
| | potentially infectious mat | terials and other conta | minants. | | | |
| | | | | In addition, these gloves were tested for use with chemotherapy | | |
| | In addition, these glo | oves were tested f | or use with | drugs in accordance with ASTM D6978 Standard Practice for | | |
| | chemotherapy drugs in | n accordance with | ASTM D6978 | · | | y Chemotherapy |
| | Standard Practice for As | sessment of Resistan | ce of Medical | Drugs: | | |
| | Gloves to Permeation by | Chemotherapy Drugs: | | | | _ |
| | | | _ | Drug and Concentration | Breakthrough | |
| | Drug and Concentration | Breakthrough | | | detection time in | |
| | | detection time in | | | minutes | |
| | | minutes | | Discoursin 45 mg/ml | (0.01µg/cm²/mins) | |
| | Place and a 15 and a 1 | (0.01µg/cm²/mins) | - | Bleomycin 15 mg/ml Busulfan 6 mg/ml | >240 >240 | - |
| | Bleomycin 15 mg/ml Busulfan 6 mg/ml | >240 >240 | 1 | Carmustine 3.3 mg/ml | 12.1 | - |
| | Carmustine 3.3 mg/ml | 26.7 | - | Cisplatin 1.0 mg/ml | >240 | - |
| | Cisplatin 1.0 mg/ml | >240 | - | Cyclophosphamide | >240 | - |
| | Cyclophosphamide | >240 | 1 | (Cytoxan) | 12.0 | |
| | (Cytoxan) | 7210 | | 20 mgl/ml | | |
| | 20 mg/ml | | | Cytarabine 100 mg/ml | >240 | |
| | Cytarabine 100 mg/ml | >240 |] | Dacarbazine (DTIC) 10 | >240 | |
| | Dacarbazine (DTIC) 10 | >240 | | mg/ml | | |
| | mg/ml | |] | Doxorubicin | >240 | |
| | | | | Hydrochloride | | |
| | | | | 2 mg/ml | | |

| | Doxorubicin | >240 | | Ellence 2 mg/ml | >240 | |
|---------------|--------------------------------------|-------------------------|-----------------|--------------------------------|------------------------|-----------------|
| | Hydrochloride | <i>7</i> 240 | | Etoposide (Toposar) 20 | >240 | |
| | 2 mg/ml | | | mg/ml | <i>></i> 240 | |
| | Ellence 2 mg/ml | >240 | | Fludarabine 25 mg/ml | >240 | |
| | Etoposide (Toposar) 20 | >240 | | Fluorouracil 50 mg/ml | >240 | |
| | mg/ml | 7210 | | Idarubicin 1 mg/ml | >240 | |
| | Fludarabine 25 mg/ml | >240 | | Ifosfamide 50 mg/ml | >240 | |
| | Fluorouracil 50 mg/ml | >240 | | Mechlorethamine HCl 1 | >240 | |
| | Idarubicin 1 mg/ml | >240 | | mg/ml | 7240 | |
| | Ifosfamide 50 mg/ml | >240 | | Melphalan 5 mg/ml | >240 | |
| | Mechlorethamine HCl 1 | >240 | | Methotrexate 25 mg/ml | >240 | |
| | mg/ml | | | Mitomycin C 0.5 mg/ml | >240 | |
| | Melphalan 5 mg/ml | >240 | | Mitoxantrone 2 mg/ml | >240 | |
| | Methotrexate 25 mg/ml | >240 | | Paclitaxel (Taxol) 6 | >240 | |
| | Mitomycin C 0.5 mg/ml | >240 | | mg/ml | | |
| | Mitoxantrone 2 mg/ml | >240 | | Paraplatin 10 mg/ml | >240 | |
| | Paclitaxel (Taxol) 6 | >240 | | Rituximab 10 mg/ml | >240 | |
| | mg/ml | | | Thiotepa 10 mg/ml | 15.5 | |
| | Paraplatin 10 mg/ml | >240 | | Trisenox 0.1 mg/ml | >240 | |
| | Rituximab 10 mg/ml | >240 | | Vincristine Sulfate 1 | >240 | |
| | Thiotepa 10 mg/ml | 28.7 | | mg/ml | | |
| | Vincristine Sulfate 1 | >240 | | | | |
| | mg/ml | | | Please note that Carmustine (3 | 3.3 mg/ml) and Thiotep | oa (10 mg/ml) |
| | | | | have much lower permeation t | | |
| | Please note that Carmustine (3 | 3.3 mg/ml) and Thiotep | a (10 mg/ml) | drugs: | | |
| | have much lower permeation | times compared to othe | er | | | |
| | chemotherapy drugs: | | | | (3.3 mg/ml) has a mini | mum |
| | | | | breakthrough time of | | |
| | | (3.3 mg/ml) has a minir | mum | |) has a minimum break | through time of |
| | breakthrough time of | | | 15.5 minutes | | |
| | ■ Thiotepa (10 mg/ml 28.7 minutes |) has a minimum breakt | through time of | | | |
| Design | Single-use | | | Single-use | | |
| 2001611 | Sterile | | | Sterile | | |
| | Powder-free | | | Powder-free | | |
| | Hand specific | | | | | |
| | Beaded cuff | | | Hand specific | | |
| N.A. taudal | | | | Beaded cuff | | |
| Material | Synthetic Polyisoprene | | | Synthetic Polyisoprene | | |
| Sterilization | Irradiation | | | Irradiation | | |
| Method | | | | | | |

| Sterility (SAL) | 10 ⁻⁶ | 10 ⁻⁶ |
|--------------------------------|--|--|
| Color | Straw (Natural) | Straw (Natural) |
| Shelf Life | 3-years | 3-years |
| Resistance to Permeation by | Meets ASTM D6978-05 (2019) | Meets ASTM D6978-05 |
| Chemotherapy | | |
| Drugs | | |
| Freedom from | AQL meets 21 CFR 800.20 and ASTM D3577-09 (2015) | AQL meets 21 CFR 800.20 and ASTM D3577-09 (2015) |
| Holes | requirements | requirements |
| Powder Residue | Meets requirements of ≤ 2.0 mg/glove for Powder-free | Meets requirements of ≤ 2.0 mg/glove for Powder-free |
| | designation per ASTM D3577-09 (2015) | designation per ASTM D3577-09 (2015) |
| Dimensions and | Meets ASTM D3577-09 (2015) | Meets ASTM D3577-09 (2015) |
| Physical | | |
| Properties | | |

Table 6-5: Technological Characteristics Comparison

| | Subject Device | | | Predicate Device | | |
|--------------------|--|--------------------------------|-----------------|---|--------------------------------|-------------------|
| Feature | Biogel® PI Indicator® Und | derglove tested for us | e with | Biogel® PI UltraTouch® G Surgical Glove tested for use with | | for use with |
| | chemotherapy agents | | | chemotherapy agents | | |
| 510(k) clearance | Previously cleared under | K081180; subject of th | nis premarket | K140477 | | |
| | notification to add "teste | d for use with chemot | herapy | | | |
| | agents" claim | | | | | |
| Manufacturer | Mölnlycke Health Care | | | Mölnlycke Health Care | | |
| Regulation | 21 CFR 878.4460, 21 CFR | 878.6250 | | 21 CFR 878.4460, 21 CFR | 878.6250 | |
| Class Name | Surgeon's Gloves | | | Surgeon's Gloves | | |
| Classification | Class I | | | Class I | | |
| Product Code | KGO, LZC | | | KGO, LZC | | |
| Indication for Use | The Skinsense polyisopre | ne underglove is a dis | posable device | Biogel® PI UltraTouch® (| G Surgical Gloves are | intended to be |
| | made of polyisoprene th | nat is intended to be | worn on the | worn on the hands, usual | y in surgical settings, t | o provide barrier |
| | hands, usually in surgical | settings, to provide a | barrier against | against potentially infecti | ous material and othe | r contaminants. |
| | potentially infectious mat | terials and other conta | aminants. | | | |
| | | | | In addition, these gloves were tested for use with chemotherapy | | |
| | In addition, these glo | oves were tested f | for use with | drugs in accordance with ASTM D6978 Standard Practice for | | |
| | chemotherapy drugs in | n accordance with | ASTM D6978 | Assessment of Medical Gloves to Permeation by Chemotherapy | | |
| | Standard Practice for As | sessment of Resistan | ce of Medical | Drugs: | | |
| | Gloves to Permeation by | Chemotherapy Drugs: | | | | |
| | | | | Drug and Concentration | Breakthrough | |
| | | | | | detection time in | |
| | Drug and Concentration | Breakthrough | | | minutes | |
| | | detection time in | | | (0.01μg/cm ² /mins) | |
| | | minutes | | Bleomycin 15 mg/ml | >240 | |
| | | (0.01μg/cm ² /mins) | _ | Busulfan 6 mg/ml | >240 | |
| | Bleomycin 15 mg/ml | >240 | - | Carmustine 3.3 mg/ml Cisplatin 1.0 mg/ml | 12.1 >240 | |
| | Busulfan 6 mg/ml | >240 | _ | Cyclophosphamide | >240 | - |
| | Carmustine 3.3 mg/ml Cisplatin 1.0 mg/ml | 17.3 | _ | (Cytoxan) | >240 | |
| | Cyclophosphamide | >240 >240 | 1 | 20 mgl/ml | | |
| | (Cytoxan) | 72 4 0 | | Cytarabine 100 mg/ml | >240 | 1 |
| | 20 mg/ml | | | Dacarbazine (DTIC) 10 | >240 | |
| | Cytarabine 100 mg/ml | >240 | 1 | mg/ml | | |
| | Dacarbazine (DTIC) 10 | >240 | 1 | Doxorubicin | >240 | |
| | mg/ml | | | Hydrochloride | | |
| | | | = | 2 mg/ml | | |

| | Doxorubicin Hydrochloride 2 mg/ml Ellence 2 mg/ml Etoposide (Toposar) 20 mg/ml Fludarabine 25 mg/ml Fluorouracil 50 mg/ml Idarubicin 1 mg/ml Ifosfamide 50 mg/ml Mechlorethamine HCl 1 | >240 >240 >240 >240 >240 >240 >240 >240 | | Ellence 2 mg/ml Etoposide (Toposar) 20 mg/ml Fludarabine 25 mg/ml Fluorouracil 50 mg/ml Idarubicin 1 mg/ml Ifosfamide 50 mg/ml Mechlorethamine HCl 1 | >240 >240 >240 >240 >240 >240 >240 | |
|----------|--|--|----------|--|--|---------------|
| | 2 mg/ml Ellence 2 mg/ml Etoposide (Toposar) 20 mg/ml Fludarabine 25 mg/ml Fluorouracil 50 mg/ml Idarubicin 1 mg/ml Ifosfamide 50 mg/ml Mechlorethamine HCl 1 | >240 >240 >240 >240 >240 >240 | | mg/ml Fludarabine 25 mg/ml Fluorouracil 50 mg/ml Idarubicin 1 mg/ml Ifosfamide 50 mg/ml | >240 >240 >240 >240 >240 | |
| | Ellence 2 mg/ml Etoposide (Toposar) 20 mg/ml Fludarabine 25 mg/ml Fluorouracil 50 mg/ml Idarubicin 1 mg/ml Ifosfamide 50 mg/ml Mechlorethamine HCl 1 | >240 >240 >240 >240 >240 >240 | | Fludarabine 25 mg/ml Fluorouracil 50 mg/ml Idarubicin 1 mg/ml Ifosfamide 50 mg/ml | >240 >240 >240 | |
| | Etoposide (Toposar) 20 mg/ml Fludarabine 25 mg/ml Fluorouracil 50 mg/ml Idarubicin 1 mg/ml Ifosfamide 50 mg/ml Mechlorethamine HCl 1 | >240 >240 >240 >240 >240 >240 | | Fluorouracil 50 mg/ml Idarubicin 1 mg/ml Ifosfamide 50 mg/ml | >240 >240 >240 | |
| | mg/ml Fludarabine 25 mg/ml Fluorouracil 50 mg/ml Idarubicin 1 mg/ml Ifosfamide 50 mg/ml Mechlorethamine HCl 1 | >240 >240 >240 >240 >240 | | Idarubicin 1 mg/ml Ifosfamide 50 mg/ml | >240 >240 | |
| | Fludarabine 25 mg/ml Fluorouracil 50 mg/ml Idarubicin 1 mg/ml Ifosfamide 50 mg/ml Mechlorethamine HCl 1 | >240 >240 >240 >240 | | Ifosfamide 50 mg/ml | >240 | |
| | Fluorouracil 50 mg/ml Idarubicin 1 mg/ml Ifosfamide 50 mg/ml Mechlorethamine HCl 1 | >240 >240 >240 >240 | | | | |
| | Idarubicin 1 mg/ml Ifosfamide 50 mg/ml Mechlorethamine HCl 1 | >240 >240 | <u> </u> | Mechlorethamine HCl 1 | | |
| | Ifosfamide 50 mg/ml Mechlorethamine HCl 1 | >240 | | | >240 | |
| | Mechlorethamine HCl 1 | | | mg/ml | | |
| | | | | Melphalan 5 mg/ml | >240 | |
| | | >240 | | Methotrexate 25 mg/ml | >240 | |
| | mg/ml | | | Mitomycin C 0.5 mg/ml | >240 | |
| | Melphalan 5 mg/ml | >240 | | Mitoxantrone 2 mg/ml | >240 | |
| | Methotrexate 25 mg/ml | >240 | | Paclitaxel (Taxol) 6 | >240 | |
| | Mitomycin C 0.5 mg/ml | >240 | | mg/ml | | |
| | Mitoxantrone 2 mg/ml | >240 | | Paraplatin 10 mg/ml | >240 | |
| | Paclitaxel (Taxol) 6 | >240 | | Rituximab 10 mg/ml | >240 | |
| | mg/ml | | | Thiotepa 10 mg/ml | 15.5 | |
| | Paraplatin 10 mg/ml | >240 | | Trisenox 0.1 mg/ml | >240 | |
| | Rituximab 10 mg/ml | >240 | | Vincristine Sulfate 1 | >240 | |
| | Thiotepa 10 mg/ml | 24.1 | | mg/ml | | |
| | Vincristine Sulfate 1 | >240 | | | | |
| | mg/ml | | _ | Please note that Carmustine (3 | 3.3 mg/ml) and Thiote | oa (10 mg/ml) |
| | breakthrough time | n times compared to oth | imum | breakthrough time | (3.3 mg/ml) has a min | mum |
| Design | Single-use | | | Single-use | | |
| | Sterile | | | Sterile | | |
| | Powder-free | | | Powder-free | | |
| | Hand specific | | | Hand specific | | |
| | Beaded cuff | | | Beaded cuff | | |
| Material | Synthetic Polyisoprene | | | Synthetic Polyisoprene | | |

| Sterilization | Irradiation | Irradiation |
|-----------------|--|--|
| Method | | |
| Sterility (SAL) | 10 ⁻⁶ | 10 ⁻⁶ |
| Color | Blue | Straw (Natural) |
| Shelf Life | 3-year | 3-year |
| Resistance to | Meets ASTM D6978-05 (2019) | Meets ASTM D6978-05 |
| Permeation by | | |
| Chemotherapy | | |
| Drugs | | |
| Freedom from | AQL meets 21 CFR 800.20 and ASTM D3577-09 (2015) | AQL meets 21 CFR 800.20 and ASTM D3577-09 (2015) |
| Holes | requirements | requirements |
| Powder Residue | Meets requirements of ≤ 2.0 mg/glove for Powder-free | Meets requirements of ≤ 2.0 mg/glove for Powder-free |
| | designation per ASTM D3577-09 (2015) | designation per ASTM D3577-09 (2015) |
| Dimensions and | Meets ASTM D3577-09 (2015) | Meets ASTM D3577-09 (2015) |
| Physical | | |
| Properties | | |

Non-clinical Testing

In support of the "tested for use with chemotherapy agents" claim, the permeation of the subject devices by specific chemotherapy drugs was evaluated according to ASTM D6978-05 (2019): Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

Clinical Data

Clinical testing was deemed not necessary to support this submission, and therefore, was not performed.

Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the subject devices are as safe, as effective, and perform as well as the legally marketed devices.