



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 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,

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)

K193573

Device Name

Biogel PI Indicator Underglove tested for use with chemotherapy agents

Indications for Use (Describe)

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.

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
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

[K193573 Indications for Use, continued]

Biogel® PI Indicator® Underglove 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	17.3
Cisplatin 1.0 mg/ml	>240
Cyclophosphamide (Cytosan) 20 mg/ml	>240
Cytarabine 100 mg/ml	>240
Dacarbazine (DTIC) 10 mg/ml	>240
Doxorubicin Hydrochloride 2 mg/ml	>240
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

Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compared to other chemotherapy drugs:

- 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)
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 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.

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
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

[K193573 Indications for Use, continued]

Biogel® PI Micro	
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	10.0
Cisplatin 1.0 mg/ml	>240
Cyclophosphamide (Cytosan) 20 mg/ml	>240
Cytarabine 100 mg/ml	>240
Dacarbazine (DTIC) 10 mg/ml	>240
Doxorubicin Hydrochloride 2 mg/ml	>240
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

Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compared to other chemotherapy drugs:

- 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)

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
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

[K193573 Indications for Use, continued]

Biogel® PI UltraTouch	
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	24.2
Cisplatin 1.0 mg/ml	>240
Cyclophosphamide (Cytosan) 20 mg/ml	>240
Cytarabine 100 mg/ml	>240
Dacarbazine (DTIC) 10 mg/ml	>240
Doxorubicin Hydrochloride 2 mg/ml	>240
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

Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compared to other chemotherapy drugs:

- 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)

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 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
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

[K193573 Indications for Use, continued]

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 (Cytosan) 20 mg/ml	>240
Cytarabine 100 mg/ml	>240
Dacarbazine (DTIC) 10 mg/ml	>240
Doxorubicin Hydrochloride 2 mg/ml	>240
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

Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compared to other chemotherapy drugs:

- 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)

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)

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
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

[K193573 Indications for Use, continued]

Biogel® Skinsense® Indicator® Underglove 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	6.6
Cisplatin 1.0 mg/ml	>240
Cyclophosphamide (Cytosan) 20 mg/ml	>240
Cytarabine 100 mg/ml	>240
Dacarbazine (DTIC) 10 mg/ml	>240
Doxorubicin Hydrochloride 2 mg/ml	>240
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

Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compared to other chemotherapy drugs:

- 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: March 23, 2020

Applicant: Mölnlycke Health Care US, LLC.
5550 Peachtree Parkway, Suite 500
Norcross, GA 30092
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: 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.

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:

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 (Cytoxan) 20 mg/ml	>240
Cytarabine 100 mg/ml	>240
Dacarbazine (DTIC) 10 mg/ml	>240
Doxorubicin Hydrochloride 2 mg/ml	>240
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

Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compared to other chemotherapy drugs:

- 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.

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:

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	10.0
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 2 mg/ml	>240
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

Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compared to other chemotherapy drugs:

- 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.

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:

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 (Cytoxan) 20 mg/ml	>240
Cytarabine 100 mg/ml	>240
Dacarbazine (DTIC) 10 mg/ml	>240
Doxorubicin Hydrochloride 2 mg/ml	>240
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

Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compared to other chemotherapy drugs:

- 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.

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:

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	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 2 mg/ml	>240
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

Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compared to other chemotherapy drugs:

- 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.

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:

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 (Cytoxan) 20 mg/ml	>240
Cytarabine 100 mg/ml	>240
Dacarbazine (DTIC) 10 mg/ml	>240
Doxorubicin Hydrochloride 2 mg/ml	>240
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

Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compared to other chemotherapy drugs:

- 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® Indicator® Underglove tested for use with chemotherapy agents	Biogel® Skinsense® Surgical Glove tested for use with chemotherapy agents																														
510(k) clearance	Originally cleared under K053102; subject of this premarket notification to add “tested for use with chemotherapy agents” claim	K140477																														
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 Use	<p>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.</p> <p>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:</p> <table border="1" data-bbox="420 1015 934 1380"> <thead> <tr> <th>Drug and Concentration</th> <th>Breakthrough detection time in minutes (0.01µg/cm²/mins)</th> </tr> </thead> <tbody> <tr> <td>Bleomycin 15 mg/ml</td> <td>>240</td> </tr> <tr> <td>Busulfan 6 mg/ml</td> <td>>240</td> </tr> <tr> <td>Carmustine 3.3 mg/ml</td> <td>6.6</td> </tr> <tr> <td>Cisplatin 1.0 mg/ml</td> <td>>240</td> </tr> <tr> <td>Cyclophosphamide (Cytosan) 20 mg/ml</td> <td>>240</td> </tr> <tr> <td>Cytarabine 100 mg/ml</td> <td>>240</td> </tr> </tbody> </table>	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 (Cytosan) 20 mg/ml	>240	Cytarabine 100 mg/ml	>240	<p>Biogel® Skinsense® Surgical Gloves are intended to be worn on the hands, usually in surgical settings, to provide barrier against potentially infectious material and other contaminants.</p> <p>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:</p> <table border="1" data-bbox="1060 917 1575 1339"> <thead> <tr> <th>Drug and Concentration</th> <th>Breakthrough detection time in minutes (0.01µg/cm²/mins)</th> </tr> </thead> <tbody> <tr> <td>Bleomycin 15 mg/ml</td> <td>>240</td> </tr> <tr> <td>Busulfan 6 mg/ml</td> <td>>240</td> </tr> <tr> <td>Carmustine 3.3 mg/ml</td> <td>60.2</td> </tr> <tr> <td>Cisplatin 1.0 mg/ml</td> <td>>240</td> </tr> <tr> <td>Cyclophosphamide (Cytosan) 20 mg/ml</td> <td>>240</td> </tr> <tr> <td>Cytarabine 100 mg/ml</td> <td>>240</td> </tr> <tr> <td>Dacarbazine (DTIC) 10 mg/ml</td> <td>>240</td> </tr> </tbody> </table>	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	60.2	Cisplatin 1.0 mg/ml	>240	Cyclophosphamide (Cytosan) 20 mg/ml	>240	Cytarabine 100 mg/ml	>240	Dacarbazine (DTIC) 10 mg/ml	>240
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 (Cytosan) 20 mg/ml	>240																															
Cytarabine 100 mg/ml	>240																															
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	60.2																															
Cisplatin 1.0 mg/ml	>240																															
Cyclophosphamide (Cytosan) 20 mg/ml	>240																															
Cytarabine 100 mg/ml	>240																															
Dacarbazine (DTIC) 10 mg/ml	>240																															

	<table border="1"> <tr><td>Dacarbazine (DTIC) 10 mg/ml</td><td>>240</td></tr> <tr><td>Doxorubicin Hydrochloride 2 mg/ml</td><td>>240</td></tr> <tr><td>Ellence 2 mg/ml</td><td>>240</td></tr> <tr><td>Etoposide (Toposar) 20 mg/ml</td><td>>240</td></tr> <tr><td>Fludarabine 25 mg/ml</td><td>>240</td></tr> <tr><td>Fluorouracil 50 mg/ml</td><td>>240</td></tr> <tr><td>Idarubicin 1 mg/ml</td><td>>240</td></tr> <tr><td>Ifosfamide 50 mg/ml</td><td>>240</td></tr> <tr><td>Mechlorethamine HCl 1 mg/ml</td><td>>240</td></tr> <tr><td>Melphalan 5 mg/ml</td><td>>240</td></tr> <tr><td>Methotrexate 25 mg/ml</td><td>>240</td></tr> <tr><td>Mitomycin C 0.5 mg/ml</td><td>>240</td></tr> <tr><td>Mitoxantrone 2 mg/ml</td><td>>240</td></tr> <tr><td>Paclitaxel (Taxol) 6 mg/ml</td><td>>240</td></tr> <tr><td>Paraplatin 10 mg/ml</td><td>>240</td></tr> <tr><td>Rituximab 10 mg/ml</td><td>>240</td></tr> <tr><td>Thiotepa 10 mg/ml</td><td>16.9</td></tr> <tr><td>Vincristine Sulfate 1 mg/ml</td><td>>240</td></tr> </table> <p>Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compared to other chemotherapy drugs:</p> <ul style="list-style-type: none"> ▪ 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 	Dacarbazine (DTIC) 10 mg/ml	>240	Doxorubicin Hydrochloride 2 mg/ml	>240	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	<table border="1"> <tr><td>Doxorubicin Hydrochloride 2 mg/ml</td><td>>240</td></tr> <tr><td>Ellence 2 mg/ml</td><td>>240</td></tr> <tr><td>Etoposide (Toposar) 20 mg/ml</td><td>>240</td></tr> <tr><td>Fludarabine 25 mg/ml</td><td>>240</td></tr> <tr><td>Fluorouracil 50 mg/ml</td><td>>240</td></tr> <tr><td>Idarubicin 1 mg/ml</td><td>>240</td></tr> <tr><td>Ifosfamide 50 mg/ml</td><td>>240</td></tr> <tr><td>Mechlorethamine HCl 1 mg/ml</td><td>>240</td></tr> <tr><td>Melphalan 5 mg/ml</td><td>>240</td></tr> <tr><td>Methotrexate 25 mg/ml</td><td>>240</td></tr> <tr><td>Mitomycin C 0.5 mg/ml</td><td>>240</td></tr> <tr><td>Mitoxantrone 2 mg/ml</td><td>>240</td></tr> <tr><td>Paclitaxel (Taxol) 6 mg/ml</td><td>>240</td></tr> <tr><td>Paraplatin 10 mg/ml</td><td>>240</td></tr> <tr><td>Rituximab 10 mg/ml</td><td>>240</td></tr> <tr><td>Thiotepa 10 mg/ml</td><td>75.8</td></tr> <tr><td>Trisenox 0.1 mg/ml</td><td>>240</td></tr> <tr><td>Vincristine Sulfate 1 mg/ml</td><td>>240</td></tr> </table> <p>Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compared to other chemotherapy drugs:</p> <ul style="list-style-type: none"> ▪ Carmustine (BCNU) (3.3 mg/ml) has a minimum breakthrough time of 60.2 minutes. ▪ Thiotepa (10 mg/ml) has a minimum breakthrough time of 75.8 minutes 	Doxorubicin Hydrochloride 2 mg/ml	>240	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	75.8	Trisenox 0.1 mg/ml	>240	Vincristine Sulfate 1 mg/ml	>240
Dacarbazine (DTIC) 10 mg/ml	>240																																																																									
Doxorubicin Hydrochloride 2 mg/ml	>240																																																																									
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																																																																									
Doxorubicin Hydrochloride 2 mg/ml	>240																																																																									
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	75.8																																																																									
Trisenox 0.1 mg/ml	>240																																																																									
Vincristine Sulfate 1 mg/ml	>240																																																																									
Design	Single-use Sterile Powder-free Hand specific Beaded cuff	Single-use Sterile Powder-free Hand specific Beaded cuff																																																																								
Material	Synthetic Polychloroprene	Synthetic Polychloroprene																																																																								

K193573

Sterilization Method	Irradiation	Irradiation
Sterility (SAL)	10 ⁻⁶	10 ⁻⁶
Color	Blue	Straw (Natural)
Shelf Life	3-years	3-years
Resistance to Permeation by Chemotherapy Drugs	Meets ASTM D6978-05 (2019)	Meets ASTM D6978-05 (2019)
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
Powder Residue	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)
Dimensions and Physical Properties	Meets ASTM D3577-09 (2015)	Meets ASTM D3577-09 (2015)

Table 6-2: Technological Characteristics Comparison

Feature	Subject Device	Predicate Device																																				
510(k) clearance	Originally cleared under K141719; subject of this premarket notification to add “tested for use with chemotherapy agents” claim	K140477																																				
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	<p>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.</p> <p>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:</p> <table border="1" data-bbox="432 922 940 1429"> <thead> <tr> <th>Drug and Concentration</th> <th>Breakthrough detection time in minutes (0.01µg/cm²/mins)</th> </tr> </thead> <tbody> <tr> <td>Bleomycin 15 mg/ml</td> <td>>240</td> </tr> <tr> <td>Busulfan 6 mg/ml</td> <td>>240</td> </tr> <tr> <td>Carmustine 3.3 mg/ml</td> <td>10.0</td> </tr> <tr> <td>Cisplatin 1.0 mg/ml</td> <td>>240</td> </tr> <tr> <td>Cyclophosphamide (Cytoxan) 20 mg/ml</td> <td>>240</td> </tr> <tr> <td>Cytarabine 100 mg/ml</td> <td>>240</td> </tr> <tr> <td>Dacarbazine (DTIC) 10 mg/ml</td> <td>>240</td> </tr> <tr> <td>Doxorubicin Hydrochloride 2 mg/ml</td> <td>>240</td> </tr> </tbody> </table>	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	10.0	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 2 mg/ml	>240	<p>Biogel® PI UltraTouch® G Surgical Gloves are intended to be worn on the hands, usually in surgical settings, to provide barrier against potentially infectious material and other contaminants.</p> <p>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:</p> <table border="1" data-bbox="1125 922 1633 1429"> <thead> <tr> <th>Drug and Concentration</th> <th>Breakthrough detection time in minutes (0.01µg/cm²/mins)</th> </tr> </thead> <tbody> <tr> <td>Bleomycin 15 mg/ml</td> <td>>240</td> </tr> <tr> <td>Busulfan 6 mg/ml</td> <td>>240</td> </tr> <tr> <td>Carmustine 3.3 mg/ml</td> <td>12.1</td> </tr> <tr> <td>Cisplatin 1.0 mg/ml</td> <td>>240</td> </tr> <tr> <td>Cyclophosphamide (Cytoxan) 20 mg/ml</td> <td>>240</td> </tr> <tr> <td>Cytarabine 100 mg/ml</td> <td>>240</td> </tr> <tr> <td>Dacarbazine (DTIC) 10 mg/ml</td> <td>>240</td> </tr> <tr> <td>Doxorubicin Hydrochloride 2 mg/ml</td> <td>>240</td> </tr> </tbody> </table>	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	12.1	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 2 mg/ml	>240
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	10.0																																					
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 2 mg/ml	>240																																					
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	12.1																																					
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 2 mg/ml	>240																																					

	<table border="1"> <tr><td>Ellence 2 mg/ml</td><td>>240</td></tr> <tr><td>Etoposide (Toposar) 20 mg/ml</td><td>>240</td></tr> <tr><td>Fludarabine 25 mg/ml</td><td>>240</td></tr> <tr><td>Fluorouracil 50 mg/ml</td><td>>240</td></tr> <tr><td>Idarubicin 1 mg/ml</td><td>>240</td></tr> <tr><td>Ifosfamide 50 mg/ml</td><td>>240</td></tr> <tr><td>Mechlorethamine HCl 1 mg/ml</td><td>>240</td></tr> <tr><td>Melphalan 5 mg/ml</td><td>>240</td></tr> <tr><td>Methotrexate 25 mg/ml</td><td>>240</td></tr> <tr><td>Mitomycin C 0.5 mg/ml</td><td>>240</td></tr> <tr><td>Mitoxantrone 2 mg/ml</td><td>>240</td></tr> <tr><td>Paclitaxel (Taxol) 6 mg/ml</td><td>>240</td></tr> <tr><td>Paraplatin 10 mg/ml</td><td>>240</td></tr> <tr><td>Rituximab 10 mg/ml</td><td>>240</td></tr> <tr><td>Thiotepa 10 mg/ml</td><td>20.3</td></tr> <tr><td>Vincristine Sulfate 1 mg/ml</td><td>>240</td></tr> </table>	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		<table border="1"> <tr><td>Ellence 2 mg/ml</td><td>>240</td></tr> <tr><td>Etoposide (Toposar) 20 mg/ml</td><td>>240</td></tr> <tr><td>Fludarabine 25 mg/ml</td><td>>240</td></tr> <tr><td>Fluorouracil 50 mg/ml</td><td>>240</td></tr> <tr><td>Idarubicin 1 mg/ml</td><td>>240</td></tr> <tr><td>Ifosfamide 50 mg/ml</td><td>>240</td></tr> <tr><td>Mechlorethamine HCl 1 mg/ml</td><td>>240</td></tr> <tr><td>Melphalan 5 mg/ml</td><td>>240</td></tr> <tr><td>Methotrexate 25 mg/ml</td><td>>240</td></tr> <tr><td>Mitomycin C 0.5 mg/ml</td><td>>240</td></tr> <tr><td>Mitoxantrone 2 mg/ml</td><td>>240</td></tr> <tr><td>Paclitaxel (Taxol) 6 mg/ml</td><td>>240</td></tr> <tr><td>Paraplatin 10 mg/ml</td><td>>240</td></tr> <tr><td>Rituximab 10 mg/ml</td><td>>240</td></tr> <tr><td>Thiotepa 10 mg/ml</td><td>15.5</td></tr> <tr><td>Trisenox 0.1 mg/ml</td><td>>240</td></tr> <tr><td>Vincristine Sulfate 1 mg/ml</td><td>>240</td></tr> </table>	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	15.5	Trisenox 0.1 mg/ml	>240	Vincristine Sulfate 1 mg/ml	>240	
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																																																																					
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	15.5																																																																					
Trisenox 0.1 mg/ml	>240																																																																					
Vincristine Sulfate 1 mg/ml	>240																																																																					
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 Method	Irradiation		Irradiation																																																																			
Sterility (SAL)	10 ⁻⁶		10 ⁻⁶																																																																			

Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compared to other chemotherapy drugs:

- 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

Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compared to other chemotherapy drugs:

- Carmustine (BCNU) (3.3 mg/ml) has a minimum breakthrough time of 12.1 minutes.
- Thiotepa (10 mg/ml) has a minimum breakthrough time of 15.5 minutes

K193573

Color	Straw (Natural)	Straw (Natural)
Shelf Life	3-years	3-years
Resistance to Permeation by Chemotherapy Drugs	Meets ASTM D6978-05 (2019)	Meets ASTM D6978-05
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
Powder Residue	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)
Dimensions and Physical Properties	Meets ASTM D3577-09 (2015)	Meets ASTM D3577-09 (2015)

Table 6-3: Technological Characteristics Comparison

Feature	Subject Device	Predicate																																				
510(k) clearance	Previously cleared under K050184; subject of this premarket notification to add “tested for use with chemotherapy agents” claim	K140477																																				
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	<p>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.</p> <p>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:</p> <table border="1"> <thead> <tr> <th>Drug and Concentration</th> <th>Breakthrough detection time in minutes (0.01µg/cm²/mins)</th> </tr> </thead> <tbody> <tr> <td>Bleomycin 15 mg/ml</td> <td>>240</td> </tr> <tr> <td>Busulfan 6 mg/ml</td> <td>>240</td> </tr> <tr> <td>Carmustine 3.3 mg/ml</td> <td>24.2</td> </tr> <tr> <td>Cisplatin 1.0 mg/ml</td> <td>>240</td> </tr> <tr> <td>Cyclophosphamide (Cytoxan) 20 mg/ml</td> <td>>240</td> </tr> <tr> <td>Cytarabine 100 mg/ml</td> <td>>240</td> </tr> <tr> <td>Dacarbazine (DTIC) 10 mg/ml</td> <td>>240</td> </tr> <tr> <td>Doxorubicin Hydrochloride 2 mg/ml</td> <td>>240</td> </tr> </tbody> </table>	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 (Cytoxan) 20 mg/ml	>240	Cytarabine 100 mg/ml	>240	Dacarbazine (DTIC) 10 mg/ml	>240	Doxorubicin Hydrochloride 2 mg/ml	>240	<p>Biogel® PI UltraTouch® G Surgical Gloves are intended to be worn on the hands, usually in surgical settings, to provide barrier against potentially infectious material and other contaminants.</p> <p>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:</p> <table border="1"> <thead> <tr> <th>Drug and Concentration</th> <th>Breakthrough detection time in minutes (0.01µg/cm²/mins)</th> </tr> </thead> <tbody> <tr> <td>Bleomycin 15 mg/ml</td> <td>>240</td> </tr> <tr> <td>Busulfan 6 mg/ml</td> <td>>240</td> </tr> <tr> <td>Carmustine 3.3 mg/ml</td> <td>12.1</td> </tr> <tr> <td>Cisplatin 1.0 mg/ml</td> <td>>240</td> </tr> <tr> <td>Cyclophosphamide (Cytoxan) 20 mg/ml</td> <td>>240</td> </tr> <tr> <td>Cytarabine 100 mg/ml</td> <td>>240</td> </tr> <tr> <td>Dacarbazine (DTIC) 10 mg/ml</td> <td>>240</td> </tr> <tr> <td>Doxorubicin Hydrochloride 2 mg/ml</td> <td>>240</td> </tr> </tbody> </table>	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	12.1	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 2 mg/ml	>240
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 (Cytoxan) 20 mg/ml	>240																																					
Cytarabine 100 mg/ml	>240																																					
Dacarbazine (DTIC) 10 mg/ml	>240																																					
Doxorubicin Hydrochloride 2 mg/ml	>240																																					
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	12.1																																					
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 2 mg/ml	>240																																					

	<table border="1"> <tr><td>Ellence 2 mg/ml</td><td>>240</td></tr> <tr><td>Etoposide (Toposar) 20 mg/ml</td><td>>240</td></tr> <tr><td>Fludarabine 25 mg/ml</td><td>>240</td></tr> <tr><td>Fluorouracil 50 mg/ml</td><td>>240</td></tr> <tr><td>Idarubicin 1 mg/ml</td><td>>240</td></tr> <tr><td>Ifosfamide 50 mg/ml</td><td>>240</td></tr> <tr><td>Mechlorethamine HCl 1 mg/ml</td><td>>240</td></tr> <tr><td>Melphalan 5 mg/ml</td><td>>240</td></tr> <tr><td>Methotrexate 25 mg/ml</td><td>>240</td></tr> <tr><td>Mitomycin C 0.5 mg/ml</td><td>>240</td></tr> <tr><td>Mitoxantrone 2 mg/ml</td><td>>240</td></tr> <tr><td>Paclitaxel (Taxol) 6 mg/ml</td><td>>240</td></tr> <tr><td>Paraplatin 10 mg/ml</td><td>>240</td></tr> <tr><td>Rituximab 10 mg/ml</td><td>>240</td></tr> <tr><td>Thiotepa 10 mg/ml</td><td>17.9</td></tr> <tr><td>Vincristine Sulfate 1 mg/ml</td><td>>240</td></tr> </table> <p>Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compared to other chemotherapy drugs:</p> <ul style="list-style-type: none"> ▪ 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 	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		<table border="1"> <tr><td>Ellence 2 mg/ml</td><td>>240</td></tr> <tr><td>Etoposide (Toposar) 20 mg/ml</td><td>>240</td></tr> <tr><td>Fludarabine 25 mg/ml</td><td>>240</td></tr> <tr><td>Fluorouracil 50 mg/ml</td><td>>240</td></tr> <tr><td>Idarubicin 1 mg/ml</td><td>>240</td></tr> <tr><td>Ifosfamide 50 mg/ml</td><td>>240</td></tr> <tr><td>Mechlorethamine HCl 1 mg/ml</td><td>>240</td></tr> <tr><td>Melphalan 5 mg/ml</td><td>>240</td></tr> <tr><td>Methotrexate 25 mg/ml</td><td>>240</td></tr> <tr><td>Mitomycin C 0.5 mg/ml</td><td>>240</td></tr> <tr><td>Mitoxantrone 2 mg/ml</td><td>>240</td></tr> <tr><td>Paclitaxel (Taxol) 6 mg/ml</td><td>>240</td></tr> <tr><td>Paraplatin 10 mg/ml</td><td>>240</td></tr> <tr><td>Rituximab 10 mg/ml</td><td>>240</td></tr> <tr><td>Thiotepa 10 mg/ml</td><td>15.5</td></tr> <tr><td>Trisenox 0.1 mg/ml</td><td>>240</td></tr> <tr><td>Vincristine Sulfate 1 mg/ml</td><td>>240</td></tr> </table> <p>Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compared to other chemotherapy drugs:</p> <ul style="list-style-type: none"> ▪ Carmustine (BCNU) (3.3 mg/ml) has a minimum breakthrough time of 12.1 minutes. ▪ Thiotepa (10 mg/ml) has a minimum breakthrough time of 15.5 minutes 	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	15.5	Trisenox 0.1 mg/ml	>240	Vincristine Sulfate 1 mg/ml	>240	
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																																																																					
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	15.5																																																																					
Trisenox 0.1 mg/ml	>240																																																																					
Vincristine Sulfate 1 mg/ml	>240																																																																					
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 Method	Irradiation		Irradiation																																																																			
Sterility (SAL)	10 ⁻⁶		10 ⁻⁶																																																																			

K193573

Color	Straw (Natural)	Straw (Natural)
Shelf Life	3-years	3-years
Resistance to Permeation by Chemotherapy Drugs	Meets ASTM D6978-05 (2019)	Meets ASTM D6978-05
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
Powder Residue	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)
Dimensions and Physical Properties	Meets ASTM D3577-09 (2015)	Meets ASTM D3577-09 (2015)

Table 6-4: Technological Characteristics Comparison

Feature	Subject Device Biogel® PI tested for use with chemotherapy agents	Predicate Device Biogel® PI UltraTouch® G Surgical Glove tested for use with chemotherapy agents																																		
510(k) clearance	Previously cleared under K050184/K053442; subject of this premarket notification to add “tested for use with chemotherapy agents” claim	K140477																																		
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	<p>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.</p> <p>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:</p> <table border="1" data-bbox="430 954 940 1373"> <thead> <tr> <th data-bbox="430 954 703 1068">Drug and Concentration</th> <th data-bbox="703 954 940 1068">Breakthrough detection time in minutes (0.01µg/cm²/mins)</th> </tr> </thead> <tbody> <tr> <td data-bbox="430 1068 703 1101">Bleomycin 15 mg/ml</td> <td data-bbox="703 1068 940 1101">>240</td> </tr> <tr> <td data-bbox="430 1101 703 1133">Busulfan 6 mg/ml</td> <td data-bbox="703 1101 940 1133">>240</td> </tr> <tr> <td data-bbox="430 1133 703 1166">Carmustine 3.3 mg/ml</td> <td data-bbox="703 1133 940 1166">26.7</td> </tr> <tr> <td data-bbox="430 1166 703 1198">Cisplatin 1.0 mg/ml</td> <td data-bbox="703 1166 940 1198">>240</td> </tr> <tr> <td data-bbox="430 1198 703 1279">Cyclophosphamide (Cytoxan) 20 mg/ml</td> <td data-bbox="703 1198 940 1279">>240</td> </tr> <tr> <td data-bbox="430 1279 703 1312">Cytarabine 100 mg/ml</td> <td data-bbox="703 1279 940 1312">>240</td> </tr> <tr> <td data-bbox="430 1312 703 1373">Dacarbazine (DTIC) 10 mg/ml</td> <td data-bbox="703 1312 940 1373">>240</td> </tr> </tbody> </table>	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	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	<p>Biogel® PI UltraTouch® G Surgical Gloves are intended to be worn on the hands, usually in surgical settings, to provide barrier against potentially infectious material and other contaminants.</p> <p>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:</p> <table border="1" data-bbox="1123 922 1633 1425"> <thead> <tr> <th data-bbox="1123 922 1396 1036">Drug and Concentration</th> <th data-bbox="1396 922 1633 1036">Breakthrough detection time in minutes (0.01µg/cm²/mins)</th> </tr> </thead> <tbody> <tr> <td data-bbox="1123 1036 1396 1068">Bleomycin 15 mg/ml</td> <td data-bbox="1396 1036 1633 1068">>240</td> </tr> <tr> <td data-bbox="1123 1068 1396 1101">Busulfan 6 mg/ml</td> <td data-bbox="1396 1068 1633 1101">>240</td> </tr> <tr> <td data-bbox="1123 1101 1396 1133">Carmustine 3.3 mg/ml</td> <td data-bbox="1396 1101 1633 1133">12.1</td> </tr> <tr> <td data-bbox="1123 1133 1396 1166">Cisplatin 1.0 mg/ml</td> <td data-bbox="1396 1133 1633 1166">>240</td> </tr> <tr> <td data-bbox="1123 1166 1396 1247">Cyclophosphamide (Cytoxan) 20 mg/ml</td> <td data-bbox="1396 1166 1633 1247">>240</td> </tr> <tr> <td data-bbox="1123 1247 1396 1279">Cytarabine 100 mg/ml</td> <td data-bbox="1396 1247 1633 1279">>240</td> </tr> <tr> <td data-bbox="1123 1279 1396 1344">Dacarbazine (DTIC) 10 mg/ml</td> <td data-bbox="1396 1279 1633 1344">>240</td> </tr> <tr> <td data-bbox="1123 1344 1396 1425">Doxorubicin Hydrochloride 2 mg/ml</td> <td data-bbox="1396 1344 1633 1425">>240</td> </tr> </tbody> </table>	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	12.1	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 2 mg/ml	>240
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	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																																			
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	12.1																																			
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 2 mg/ml	>240																																			

	<table border="1"> <tr><td>Doxorubicin Hydrochloride 2 mg/ml</td><td>>240</td></tr> <tr><td>Ellence 2 mg/ml</td><td>>240</td></tr> <tr><td>Etoposide (Toposar) 20 mg/ml</td><td>>240</td></tr> <tr><td>Fludarabine 25 mg/ml</td><td>>240</td></tr> <tr><td>Fluorouracil 50 mg/ml</td><td>>240</td></tr> <tr><td>Idarubicin 1 mg/ml</td><td>>240</td></tr> <tr><td>Ifosfamide 50 mg/ml</td><td>>240</td></tr> <tr><td>Mechlorethamine HCl 1 mg/ml</td><td>>240</td></tr> <tr><td>Melphalan 5 mg/ml</td><td>>240</td></tr> <tr><td>Methotrexate 25 mg/ml</td><td>>240</td></tr> <tr><td>Mitomycin C 0.5 mg/ml</td><td>>240</td></tr> <tr><td>Mitoxantrone 2 mg/ml</td><td>>240</td></tr> <tr><td>Paclitaxel (Taxol) 6 mg/ml</td><td>>240</td></tr> <tr><td>Paraplatin 10 mg/ml</td><td>>240</td></tr> <tr><td>Rituximab 10 mg/ml</td><td>>240</td></tr> <tr><td>Thiotepa 10 mg/ml</td><td>28.7</td></tr> <tr><td>Vincristine Sulfate 1 mg/ml</td><td>>240</td></tr> </table>	Doxorubicin Hydrochloride 2 mg/ml	>240	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		<table border="1"> <tr><td>Ellence 2 mg/ml</td><td>>240</td></tr> <tr><td>Etoposide (Toposar) 20 mg/ml</td><td>>240</td></tr> <tr><td>Fludarabine 25 mg/ml</td><td>>240</td></tr> <tr><td>Fluorouracil 50 mg/ml</td><td>>240</td></tr> <tr><td>Idarubicin 1 mg/ml</td><td>>240</td></tr> <tr><td>Ifosfamide 50 mg/ml</td><td>>240</td></tr> <tr><td>Mechlorethamine HCl 1 mg/ml</td><td>>240</td></tr> <tr><td>Melphalan 5 mg/ml</td><td>>240</td></tr> <tr><td>Methotrexate 25 mg/ml</td><td>>240</td></tr> <tr><td>Mitomycin C 0.5 mg/ml</td><td>>240</td></tr> <tr><td>Mitoxantrone 2 mg/ml</td><td>>240</td></tr> <tr><td>Paclitaxel (Taxol) 6 mg/ml</td><td>>240</td></tr> <tr><td>Paraplatin 10 mg/ml</td><td>>240</td></tr> <tr><td>Rituximab 10 mg/ml</td><td>>240</td></tr> <tr><td>Thiotepa 10 mg/ml</td><td>15.5</td></tr> <tr><td>Trisenox 0.1 mg/ml</td><td>>240</td></tr> <tr><td>Vincristine Sulfate 1 mg/ml</td><td>>240</td></tr> </table>	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	15.5	Trisenox 0.1 mg/ml	>240	Vincristine Sulfate 1 mg/ml	>240	<p>Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compared to other chemotherapy drugs:</p> <ul style="list-style-type: none"> ▪ Carmustine (BCNU) (3.3 mg/ml) has a minimum breakthrough time of 12.1 minutes. ▪ Thiotepa (10 mg/ml) has a minimum breakthrough time of 15.5 minutes
Doxorubicin Hydrochloride 2 mg/ml	>240																																																																							
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																																																																							
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	15.5																																																																							
Trisenox 0.1 mg/ml	>240																																																																							
Vincristine Sulfate 1 mg/ml	>240																																																																							
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 Method	Irradiation		Irradiation																																																																					

K193573

Sterility (SAL)	10 ⁻⁶	10 ⁻⁶
Color	Straw (Natural)	Straw (Natural)
Shelf Life	3-years	3-years
Resistance to Permeation by Chemotherapy Drugs	Meets ASTM D6978-05 (2019)	Meets ASTM D6978-05
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
Powder Residue	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)
Dimensions and Physical Properties	Meets ASTM D3577-09 (2015)	Meets ASTM D3577-09 (2015)

Table 6-5: Technological Characteristics Comparison

Feature	Subject Device	Predicate Device																																		
510(k) clearance	Previously cleared under K081180; subject of this premarket notification to add “tested for use with chemotherapy agents” claim	K140477																																		
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	<p>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.</p> <p>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:</p> <table border="1" data-bbox="430 987 940 1406"> <thead> <tr> <th>Drug and Concentration</th> <th>Breakthrough detection time in minutes (0.01µg/cm²/mins)</th> </tr> </thead> <tbody> <tr> <td>Bleomycin 15 mg/ml</td> <td>>240</td> </tr> <tr> <td>Busulfan 6 mg/ml</td> <td>>240</td> </tr> <tr> <td>Carmustine 3.3 mg/ml</td> <td>17.3</td> </tr> <tr> <td>Cisplatin 1.0 mg/ml</td> <td>>240</td> </tr> <tr> <td>Cyclophosphamide (Cytoxan) 20 mg/ml</td> <td>>240</td> </tr> <tr> <td>Cytarabine 100 mg/ml</td> <td>>240</td> </tr> <tr> <td>Dacarbazine (DTIC) 10 mg/ml</td> <td>>240</td> </tr> </tbody> </table>	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 (Cytoxan) 20 mg/ml	>240	Cytarabine 100 mg/ml	>240	Dacarbazine (DTIC) 10 mg/ml	>240	<p>Biogel® PI UltraTouch® G Surgical Gloves are intended to be worn on the hands, usually in surgical settings, to provide barrier against potentially infectious material and other contaminants.</p> <p>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:</p> <table border="1" data-bbox="1123 922 1633 1422"> <thead> <tr> <th>Drug and Concentration</th> <th>Breakthrough detection time in minutes (0.01µg/cm²/mins)</th> </tr> </thead> <tbody> <tr> <td>Bleomycin 15 mg/ml</td> <td>>240</td> </tr> <tr> <td>Busulfan 6 mg/ml</td> <td>>240</td> </tr> <tr> <td>Carmustine 3.3 mg/ml</td> <td>12.1</td> </tr> <tr> <td>Cisplatin 1.0 mg/ml</td> <td>>240</td> </tr> <tr> <td>Cyclophosphamide (Cytoxan) 20 mg/ml</td> <td>>240</td> </tr> <tr> <td>Cytarabine 100 mg/ml</td> <td>>240</td> </tr> <tr> <td>Dacarbazine (DTIC) 10 mg/ml</td> <td>>240</td> </tr> <tr> <td>Doxorubicin Hydrochloride 2 mg/ml</td> <td>>240</td> </tr> </tbody> </table>	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	12.1	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 2 mg/ml	>240
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 (Cytoxan) 20 mg/ml	>240																																			
Cytarabine 100 mg/ml	>240																																			
Dacarbazine (DTIC) 10 mg/ml	>240																																			
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	12.1																																			
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 2 mg/ml	>240																																			

	<table border="1"> <tr><td>Doxorubicin Hydrochloride 2 mg/ml</td><td>>240</td></tr> <tr><td>Ellence 2 mg/ml</td><td>>240</td></tr> <tr><td>Etoposide (Toposar) 20 mg/ml</td><td>>240</td></tr> <tr><td>Fludarabine 25 mg/ml</td><td>>240</td></tr> <tr><td>Fluorouracil 50 mg/ml</td><td>>240</td></tr> <tr><td>Idarubicin 1 mg/ml</td><td>>240</td></tr> <tr><td>Ifosfamide 50 mg/ml</td><td>>240</td></tr> <tr><td>Mechlorethamine HCl 1 mg/ml</td><td>>240</td></tr> <tr><td>Melphalan 5 mg/ml</td><td>>240</td></tr> <tr><td>Methotrexate 25 mg/ml</td><td>>240</td></tr> <tr><td>Mitomycin C 0.5 mg/ml</td><td>>240</td></tr> <tr><td>Mitoxantrone 2 mg/ml</td><td>>240</td></tr> <tr><td>Paclitaxel (Taxol) 6 mg/ml</td><td>>240</td></tr> <tr><td>Paraplatin 10 mg/ml</td><td>>240</td></tr> <tr><td>Rituximab 10 mg/ml</td><td>>240</td></tr> <tr><td>Thiotepa 10 mg/ml</td><td>24.1</td></tr> <tr><td>Vincristine Sulfate 1 mg/ml</td><td>>240</td></tr> </table>	Doxorubicin Hydrochloride 2 mg/ml	>240	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	<p>Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compared to other chemotherapy drugs:</p> <ul style="list-style-type: none"> ▪ 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 border="1"> <tr><td>Ellence 2 mg/ml</td><td>>240</td></tr> <tr><td>Etoposide (Toposar) 20 mg/ml</td><td>>240</td></tr> <tr><td>Fludarabine 25 mg/ml</td><td>>240</td></tr> <tr><td>Fluorouracil 50 mg/ml</td><td>>240</td></tr> <tr><td>Idarubicin 1 mg/ml</td><td>>240</td></tr> <tr><td>Ifosfamide 50 mg/ml</td><td>>240</td></tr> <tr><td>Mechlorethamine HCl 1 mg/ml</td><td>>240</td></tr> <tr><td>Melphalan 5 mg/ml</td><td>>240</td></tr> <tr><td>Methotrexate 25 mg/ml</td><td>>240</td></tr> <tr><td>Mitomycin C 0.5 mg/ml</td><td>>240</td></tr> <tr><td>Mitoxantrone 2 mg/ml</td><td>>240</td></tr> <tr><td>Paclitaxel (Taxol) 6 mg/ml</td><td>>240</td></tr> <tr><td>Paraplatin 10 mg/ml</td><td>>240</td></tr> <tr><td>Rituximab 10 mg/ml</td><td>>240</td></tr> <tr><td>Thiotepa 10 mg/ml</td><td>15.5</td></tr> <tr><td>Trisenox 0.1 mg/ml</td><td>>240</td></tr> <tr><td>Vincristine Sulfate 1 mg/ml</td><td>>240</td></tr> </table>	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	15.5	Trisenox 0.1 mg/ml	>240	Vincristine Sulfate 1 mg/ml	>240	<p>Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compared to other chemotherapy drugs:</p> <ul style="list-style-type: none"> ▪ Carmustine (BCNU) (3.3 mg/ml) has a minimum breakthrough time of 12.1 minutes. ▪ Thiotepa (10 mg/ml) has a minimum breakthrough time of 15.5 minutes
Doxorubicin Hydrochloride 2 mg/ml	>240																																																																							
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																																																																							
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	15.5																																																																							
Trisenox 0.1 mg/ml	>240																																																																							
Vincristine Sulfate 1 mg/ml	>240																																																																							
Design	Single-use Sterile Powder-free Hand specific Beaded cuff		Single-use Sterile Powder-free Hand specific Beaded cuff																																																																					
Material	Synthetic Polyisoprene		Synthetic Polyisoprene																																																																					

K193573

Sterilization Method	Irradiation	Irradiation
Sterility (SAL)	10 ⁻⁶	10 ⁻⁶
Color	Blue	Straw (Natural)
Shelf Life	3-year	3-year
Resistance to Permeation by Chemotherapy Drugs	Meets ASTM D6978-05 (2019)	Meets ASTM D6978-05
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
Powder Residue	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)
Dimensions and Physical Properties	Meets ASTM D3577-09 (2015)	Meets ASTM D3577-09 (2015)

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.