November 22, 2020

Molnlycke Health Care, US LLC
Leonard Stewart
Regulatory Affairs Specialist
5445 Triangle Parkway, Suite 400
Peachtree Corners, Georgia 30092

Re: K202090
Trade/Device Name: Biogel Eclipse Natural Rubber Latex Surgical Gloves tested for use with chemotherapy agents; Biogel® Eclipse Indicator Underglove Green natural rubber latex surgical indicator underglove tested for use with chemotherapy agents; Biogel® Surgeons Natural rubber latex surgical gloves tested for use with chemotherapy agents; Biogel® Indicator Underglove Green natural rubber latex surgical indicator underglove tested for use with chemotherapy agents; Biogel® PI Micro Indicator Underglove Blue polyisoprene surgical indicator underglove tested for use with chemotherapy agents; Biogel® PI Ultra Touch S Polyisoprene surgical gloves for reduced risk of Type IV allergic contact dermatitis Tested for use with chemotherapy agents; Biogel® PI UltraTouch S Indicator Underglove Blue polyisoprene surgical indicator underglove for reduced risk of Type IV allergic contact dermatitis 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: July 24, 2020
Received: July 28, 2020

Dear Leonard Stewart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration,

listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,
For: Elizabeth F. Claverie, MS
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202090

Device Name
Biogel Eclipse Natural Rubber Latex Surgical Gloves tested for use with chemotherapy agents

Indications for Use *(Describe)*
The Biogel Eclipse Natural Rubber Latex Surgical Gloves tested for use with chemotherapy agents is a disposable device made of natural rubber latex, that is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious material and other contaminants.

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)

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Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@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."

Drug and Concentration	Breakthrough detection time in minutes ($0.01\mu g/cm^2$/mins)
Bleomycin 15 mg/ml	>240
Busulfan 6 mg/ml	>240
Carmustine 3.3 mg/ml	12.1
Cisplatin 1 mg/ml	>240
Cyclophosphamide (Cytoxan) 20 mg/ml	>240
Cytarabine HCL 100 mg/ml	>240
Dacarbazine (DTIC) 10 mg/ml	>240
Doxorubicin HCL 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	14.1
Vincristine Sulfate 1 mg/ml	>240

Warning: Do not use single gloves for protection against Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml). Consider using multiple gloves with longer breakthrough detection times.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K202090

Device Name
Biogel® Eclipse Indicator Underglove Green natural rubber latex surgical indicator underglove tested for use with chemotherapy agents

Indications for Use *(Describe)*
The Biogel® Eclipse Indicator Underglove Green natural rubber latex surgical indicator underglove tested for use with chemotherapy agents is a disposable device made of natural rubber latex, that is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious material and other contaminants.

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)

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Drug and Concentration	Breakthrough detection time in minutes ($0.01\mu g/cm^2$/mins)
Bleomycin 15 mg/ml	>240
Busulfan 6 mg/ml	>240
Carmustine 3.3 mg/ml	11.7
Cisplatin 1 mg/ml	>240
Cyclophosphamide (Cytoxan) 20 mg/ml	>240
Cytarabine HCL 100 mg/ml	>240
Dacarbazine (DTIC) 10 mg/ml	>240
Doxorubicin HCL 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	15.6
Vincristine Sulfate 1 mg/ml	>240

Warning: Do not use single gloves for protection against Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml). Consider using multiple gloves with longer breakthrough detection times.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202090

Device Name
Biogel® Surgeons Natural rubber latex surgical gloves tested for use with chemotherapy agents

Indications for Use *(Describe)*
The Biogel® Surgeons Natural rubber latex surgical gloves tested for use with chemotherapy agents is a disposable device made of natural rubber latex, that is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious material and other contaminants.

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)

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Drug and Concentration	Breakthrough detection time in minutes ($0.01\mu g/cm^2$/mins)
Bleomycin 15 mg/ml	>240
Busulfan 6 mg/ml	>240
Carmustine 3.3 mg/ml	14.0
Cisplatin 1 mg/ml	>240
Cyclophosphamide (Cytoxan) 20 mg/ml	>240
Cytarabine HCL 100 mg/ml	>240
Dacarbazine (DTIC) 10 mg/ml	>240
Doxorubicin HCL 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	23.5
Vincristine Sulfate 1 mg/ml	>240

Warning: Do not use single gloves for protection against Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml). Consider using multiple gloves with longer breakthrough detection times.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K202090

Device Name
Biogel® Indicator Underglove Green natural rubber latex surgical indicator underglove tested for use with chemotherapy agents

Indications for Use *(Describe)*
Biogel® Indicator Underglove Green natural rubber latex surgical indicator underglove tested for use with chemotherapy agents is a disposable device made of natural rubber latex, that is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious material and other contaminants.

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)

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Drug and Concentration	Breakthrough detection time in minutes ($0.01\mu g/cm^2$/mins)
Bleomycin 15 mg/ml	>240
Busulfan 6 mg/ml	>240
Carmustine 3.3 mg/ml	5.3
Cisplatin 1 mg/ml	>240
Cyclophosphamide (Cytoxan) 20 mg/ml	>240
Cytarabine HCL 100 mg/ml	>240
Dacarbazine (DTIC) 10 mg/ml	>240
Doxorubicin HCL 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	13.1
Vincristine Sulfate 1 mg/ml	>240

Warning: Do not use single gloves for protection against Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml). Consider using multiple gloves with longer breakthrough detection times.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202090

Device Name
Biogel® PI Micro Indicator Underglove Blue polyisoprene surgical indicator underglove tested for use with chemotherapy agents

Indications for Use *(Describe)*

The Biogel® PI Micro Indicator Underglove Blue polyisoprene surgical indicator underglove tested for use with chemotherapy agents is a disposable device made of polyisoprene, blue in color, that is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious material and other contaminants.

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)

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Drug and Concentration	Breakthrough detection time in minutes ($0.01\mu g/cm^2$/mins)
Bleomycin 15 mg/ml	>240
Busulfan 6 mg/ml	>240
Carmustine 3.3 mg/ml	13.2
Cisplatin 1 mg/ml	>240
Cyclophosphamide (Cytoxan) 20 mg/ml	>240
Cytarabine HCL 100 mg/ml	>240
Dacarbazine (DTIC) 10 mg/ml	>240
Doxorubicin HCL 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	22.3
Vincristine Sulfate 1 mg/ml	>240

Warning: Do not use single gloves for protection against Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml). Consider using multiple gloves with longer breakthrough detection times.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202090

Device Name
Biogel® PI UltraTouch S Polyisoprene surgical gloves for reduced risk of Type IV allergic contact dermatitis Tested for use with chemotherapy agents

Indications for Use *(Describe)*
The Biogel® PI UltraTouch S Polyisoprene surgical gloves for reduced risk of Type IV allergic contact dermatitis Tested for use with chemotherapy agents is a disposable device made of polyisoprene, blue in color, that is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious material and other contaminants.

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.

Drug and Concentration	Breakthrough detection time in minutes ($0.01\mu g/cm^2$/mins)
Bleomycin 15 mg/ml	>240
Busulfan 6 mg/ml	>240
Carmustine 3.3 mg/ml	14.3
Cisplatin 1 mg/ml	>240
Cyclophosphamide (Cytoxan) 20 mg/ml	>240
Cytarabine HCL 100 mg/ml	>240
Dacarbazine (DTIC) 10 mg/ml	>240
Doxorubicin HCL 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	26.8
Vincristine Sulfate 1 mg/ml	>240

Warning: Do not use single gloves for protection against Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml). Consider using multiple gloves with longer breakthrough detection times.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202090

Device Name
Biogel® PI UltraTouch S Indicator Underglove Blue polyisoprene surgical indicator underglove for reduced risk of Type IV allergic contact dermatitis Tested for use with chemotherapy agents

Indications for Use *(Describe)*
The Biogel® PI UltraTouch S Indicator Underglove Blue polyisoprene surgical indicator underglove for reduced risk of Type IV allergic contact dermatitis Tested for use with chemotherapy agents is a disposable device made of polyisoprene, blue in color, that is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious material and other contaminants

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)

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Drug and Concentration	Breakthrough detection time in minutes ($0.01\mu g/cm^2$/mins)
Bleomycin 15 mg/ml	>240
Busulfan 6 mg/ml	>240
Carmustine 3.3 mg/ml	15.2
Cisplatin 1 mg/ml	>240
Cyclophosphamide (Cytoxan) 20 mg/ml	>240
Cytarabine HCL 100 mg/ml	>240
Dacarbazine (DTIC) 10 mg/ml	>240
Doxorubicin HCL 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	17.8
Vincristine Sulfate 1 mg/ml	>240

Warning: Do not use single gloves for protection against Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml). Consider using multiple gloves with longer breakthrough detection times.