August 19, 2025

HARPS Europe Manufacturing GmbH
% Jay Mansour
Regulatory consultant / Principal
Mansour Consulting LLC
845 Aronson Lake Court
Roswell, Georgia 30075

Re: K250313
Trade/Device Name: Sterile Powder Free Synthetic Rubber Surgeon's Gloves, Green Color, Tested For Use With Chemotherapy Drugs and Gastric Acid
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO, LZC
Dated: February 3, 2025
Received: July 21, 2025

Dear Jay Mansour:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

ALLAN GUAN -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection Control 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

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below

510(k) Number *(if known)*
K250313

Device Name
Sterile Powder Free Synthetic Rubber Surgeon's Gloves, Green Color, Tested For Use With Chemotherapy Drugs and Gastric Acid

Indications for Use *(Describe)*
The Sterile Powder Free Synthetic Rubber Surgeon's Gloves, Green Color, Tested For Use With Chemotherapy Drugs and Gastric Acid is a single use disposable device intended to be worn by operating room personnel to protect a surgical wound from contamination.

The tested drugs are:

Compound	Minimum Breakthrough Time (minutes)
Carmustine (BCNU) (3.3 mg/ml)	15.8
Cyclophosphamide (20 mg/ml)	>240
Doxorubicin (2 mg/ml)	>240
Etoposide (Toposar) (20 mg/ml)	>240
Fluorouracil (50 mg/ml)	>240
Paclitaxel (6 mg/ml)	>240
Thiotepa (THT) (10 mg/ml)	24.6
Bleomycin sulfate (15 mg/ml)	>240
Carboplatin (10 mg/ml)	>240
Cisplatin (1 mg/ml)	>240
Cytarabine (100 mg/ml)	>240
Dacarbazine (10 mg/ml)	>240
Daunorubicin HCl (5 mg/ml)	>240
Docetaxel (10 mg/ml)	>240
Gemcitabine HCl (38 mg/ml)	>240
Idarubicin HCl (1 mg/ml)	>240
Ifosfamide (50 mg/ml)	>240
Irinotecan HCl (20 mg/ml)	>240
Mechlorethamine HCl (1 mg/ml)	>240
Melphalan HCl (5 mg/ml)	>240
Methotrexate (25 mg/ml)	>240
Mitomycin C (0.5 mg/ml)	>240
Mitoxantrone (2 mg/ml)	>240
Vincristine Sulfate (1 mg/ml)	>240
Busulfan (6 mg/ml)	>240
Chloroquine (50 mg/ml)	>240
Cyclosporin A (100 mg/ml)	>240
Epirubicin HCl (2 mg/ml)	>240
Fludarabine Phosphate (25 mg/ml)	>240
Oxaliplatin (2 mg/ml)	>240
Retrovir (10 mg/ml)	>240
Rituximab (10 mg/ml)	>240
Topotecan HCl (1 mg/ml)	>240
Trisenox (Arsenic Trioxide) (1 mg/ml)	>240
Velcade (Bortezomib) (1 mg/ml)	>240

Simulated Gastric Acid Fluid was also tested with a minimum breakthrough greater than 240 minutes.

WARNING:
Please note the following drugs have extremely low permeation times:
Carmustine: 15.8 minutes and Thiotepa: 24.6 minutes. Do not use with Carmustine and Thiotepa.

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.

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510K Summary

510(k) Number: K250313

Submitter: HARPS Europe Manufacturing GmbH
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Date Prepared: 2025-08-14

Name of Device

Trade Names: Sterile Powder Free Synthetic Rubber Surgeon's Gloves, Green Color, Tested For Use With Chemotherapy Drugs and Gastric Acid

Common Name: Non-powdered surgeon's glove

Classification Name: Surgeon's Gloves

Classification Regulation: 21 CFR 878.4460

Device Class: I

Product Code: KGO, LZC

Classification Panel: General and Plastic Surgery

Legally Marketed Predicate Device

Primary Predicate: K160781

Sempermed Syntegra IR, Sterile Powder Free Synthetic Rubber Surgeons Gloves

Device Description

Sterile Powder Free Synthetic Rubber Surgeon's Gloves, Green Color, Tested For Use With Chemotherapy Drugs and Gastric Acid is a sterile and disposable device. This glove is made of synthetic polyisoprene rubber inside coated with synthetic material to ease donning the glove. The device is intended to be worn on hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants. These gloves were tested for use with Chemotherapy Drugs and Gastric Acid as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

The device conforms to the following FDA recognized consensus standards: ASTM D3577-19, ASTM D6124-06, ASTM D5151-19, ASTM D412-16, ISO 11137-1:2006 + AMD1:2013 + AMD2:2018, ISO 11137-2:2013 + AMD1:2022, and ASTM D6978-05.

Sterile Powder Free Synthetic Rubber Surgeon's Gloves, Green Color, Tested For Use With Chemotherapy Drugs and Gastric Acid is available in the following sizes: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, and 9.0.

Indication for Use Statement

The Sterile Powder Free Synthetic Rubber Surgeon's Gloves, Green Color, Tested For Use With Chemotherapy Drugs and Gastric Acid is a single use disposable device intended to be worn by operating room personnel to protect a surgical wound from contamination.
The tested drugs are:

Compound	Minimum Breakthrough Time (minutes)
Carmustine (BCNU) (3.3 mg/ml)	15.8
Cyclophosphamide (20 mg/ml)	>240
Doxorubicin (2 mg/ml)	>240
Etoposide (Toposar) (20 mg/ml)	>240
Fluorouracil (50 mg/ml)	>240
Paclitaxel (6 mg/ml)	>240
Thiotepa (THT) (10 mg/ml)	24.6
Bleomycin sulfate (15 mg/ml)	>240
Carboplatin (10 mg/ml)	>240
Cisplatin (1 mg/ml)	>240
Cytarabine (100 mg/ml)	>240
Dacarbazine (10 mg/ml)	>240
Daunorubicin HCl (5 mg/ml)	>240
Docetaxel (10 mg/ml)	>240
Gemcitabine HCl (38 mg/ml)	>240
Idarubicin HCl (1 mg/ml)	>240
Ifosfamide (50 mg/ml)	>240
Irinotecan HCl (20 mg/ml)	>240
Mechlorethamine HCl (1 mg/ml)	>240
Melphalan HCl (5 mg/ml)	>240
Methotrexate (25 mg/ml)	>240

Mitomycin C (0.5 mg/ml)	>240
Mitoxantrone (2 mg/ml)	>240
Vincristine Sulfate (1 mg/ml)	>240
Busulfan (6 mg/ml)	>240
Chloroquine (50 mg/ml)	>240
Cyclosporin A (100 mg/ml)	>240
Epirubicin HCl (2 mg/ml)	>240
Fludarabine Phosphate (25 mg/ml)	>240
Oxaliplatin (2 mg/ml)	>240
Retrovir (10 mg/ml)	>240
Rituximab (10 mg/ml)	>240
Topotecan HCl (1 mg/ml)	>240
Trisenox (Arsenic Trioxide) (1 mg/ml)	>240
Velcade (Bortezomib) (1 mg/ml)	>240

Simulated Gastric Acid Fluid was also tested with a minimum breakthrough greater than 240 minutes.
WARNING:
Please note the following drugs have extremely low permeation times:
Carmustine: 15.8 minutes and Thiotepa: 24.6 minutes. Do not use with Carmustine and Thiotepa.

Technological Characteristics

	Predicate Device	Subject Device	Comparison
Trade name	Sempermed Syntegra IR, Sterile Powder Free Synthetic Rubber Surgeons Gloves	Sterile Powder Free Synthetic Rubber Surgeon's Gloves, Green Color, Tested For Use With Chemotherapy Drugs and Gastric Acid	Different
510k Number	K160781	K250313	Different
Product Owner	Sempermed USA Inc.	HARPS Europe Manufacturing GmbH	Different
Product Code	KGO	KGO, LZC	Same
Regulation Number	21 CFR 878.4460	21 CFR 878.4460	Same
Regulatory Class	I	I	Same
Regulation Name	Non-powdered Surgeon's Gloves	Non-powdered Surgeon's glove	Same
Indications For Use	The Sterile Powder Free Synthetic Rubber Gloves is a single use disposable device intended to be worn by operating room	The Sterile Powder Free Synthetic Rubber Surgeon's Gloves, Green Color, Tested For Use With Chemotherapy	Different - Added chemotherapy and gastric acid testing

	personnel to protect a surgical wound from contamination.	Drugs and Gastric Acid is a single use disposable device intended to be worn by operating room personnel to protect a surgical wound from contamination. The tested drugs are: (table of tested drugs removed for clarity) Simulated Gastric Acid Fluid was also tested with a minimum breakthrough greater than 240 minutes. WARNING: Please note the following drugs have extremely low permeation times: Carmustine: 15.8 minutes and Thiotepa: 24.6 minutes. Do not use with Carmustine and Thiotepa.	
Material	Synthetic polyisoprene rubber	Synthetic polyisoprene rubber	Similar
Coating	Synthetic polymeric inner coating	Synthetic polymeric inner coating	Similar
Design	Single use	Single use	Same
Design	Powder-free	Powder-free	Same
Design	Anatomical shape with curved fingers	Anatomical shape with curved fingers	Same
Design	Beaded cuff	Beaded cuff	Same
Color	Natural color	Green	Different
Labeling	Surgeon's Gloves	Surgeon's Gloves	Similar
Shelf Life	Not specified	No claimed shelf life	Similar

Sterility Assurance Level	10^{-6}	10^{-6}	Same
Sterilization Modality	Not specified	Radiation	Different
Surgical Glove ASTM D3577	Meets requirements	Meets requirements	Same
Dimensions ASTM D3577	5½, 6, 6½, 7, 7½, 8, 8½, and 9	5½, 6, 6½, 7, 7½, 8, 8½, and 9	Same
Tensile Strength Before Aging ASTM D3577	17 MPa min	17 MPa min	Same
Ultimate Elongation Before Aging ASTM D3577	650% min	650% min	Same
Stress at 500% Elongation Before Aging	7.0 MPa min	7.0 MPa min	Same
Tensile Strength After Aging ASTM D3577	12 MPa min	12 MPa min	Same
Ultimate Elongation After Aging	490 % min	490 % min	Same
Residual Powder ASTM D6124	Does not exceed 2 mg/glove	Does not exceed 2 mg/glove	Same
Freedom From Holes ASTM D5151	Meets ASTM D3577 requirements	Meets ASTM D3577 requirements	Same
Biocompatibility In Vitro Cytotoxicity ISO 10993-5	Not specified	Under the conditions of the study, failed with cytotoxicity grade 4	Same
Biocompatibility Primary Skin Irritation ISO 10993-10	Under the conditions of the study, the device is not an irritant.	Under the conditions of the study, the device is not an irritant.	Same
Biocompatibility Dermal Sensitization - ISO 10993-10	Under the conditions of the study, the device is a non-sensitizer.	Under the conditions of the study, the device is a non-sensitizer.	Same
Biocompatibility Systemic Toxicity ISO 10993-11	Not specified	Under the conditions of the study, the device does not exhibit	Different

		acute systemic toxicity.	
Biocompatibility Material Mediated Toxicity ISO 10993-11:2017	Not specified	Under the conditions of the study, no pyrogenic response was observed.	Different
Biocompatibility Bacterial Endotoxins Test USP <85>	Not specified	Under conditions of the study, less than 20 EU/device	Different

Comparison Between Predicate and Proposed:

Differences in Trade Name, 510k Number, Product Owner, Color, and Sterilization Modality do not directly affect the performance or use of the devices.

Chemotherapy Testing: The predicate device was not tested for permeation of chemotherapy drugs or gastric acid. The safety and efficacy of the proposed device with respect to chemotherapy drugs and gastric acid is addressed through the performance testing and labeling of the device.

Shelf Life: There is no claimed shelf life for the proposed device.

The subject and predicate devices meet the applicable requirements for surgeon's gloves with regards to dimensions and sizes, physical properties, freedom from holes, and powder residues as found in the following standards: ASTM D3577, ASTM D5151 and ASTM D6124. The subject device passes biological reactivity testing for dermal sensitization, irritation, acute systemic toxicity, and material-mediated pyrogenicity in accord with the ISO 10993 series of standards.

Non-Clinical Testing

Sterile Powder Free Synthetic Rubber Surgeon's Gloves, Green Color, Tested For Use With Chemotherapy Drugs and Gastric Acid has the following technological characteristics as compared to ASTM or equivalent standards:

Title of Test	Purpose of Test	Acceptance Criteria	Results
ASTM D3577-19	Dimensions	Meets criteria in accordance with ASTM D3577-19: Standard Specification for Rubber Surgical Gloves	PASS
ASTM D3577-19	Physical Properties	Meets criteria for tensile strength, ultimate elongation and stress at 500% elongation before and after accelerated aging for synthetic surgical	PASS

		gloves per ASTM D3577-19: Standard Specification for Rubber Surgical Gloves	
ASTM D5151-19	Freedom from holes	Meets criteria in accordance with ASTM D3577-19: Standard Specification for Rubber Surgical Gloves with AQL requirements of 0.65	PASS
ASTM D6124	Powder-Free	Meets applicable acceptance criteria for powder free ≤ 2mg per glove per ASTM D3577-19: Standard Specification for Rubber Surgical Gloves	PASS
ISO 11137-1:2006	Sterility	Meets acceptance criteria requirement of 10^{-6} SAL per ISO 11137-1: Sterilization for health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	PASS
ASTM D6978-05	Chemotherapy Drug Permeation Test	Testing performed in accordance with ASTM D6978-05: Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.	PASS
ISO 10993-10:2010	Biocompatibility: Skin Irritation	Passes Primary Skin Irritation test per ISO 10993-10, Biological Evaluation of medical devices, Part 10: Test for irritation and skin sensitization. Under the conditions of the study, not an irritant.	PASS
ISO 10993-10:2010	Biocompatibility: Dermal Sensitization	Passes Dermal Sensitization test per ISO 10993-10, Biological Evaluation of medical devices, Part 10: Test for irritation and skin sensitization. Under the conditions of the study, not a sensitizer.	PASS

ISO 10993-11:2017	Biocompatibility: Acute Systemic Toxicity	Passes Acute Systemic Toxicity Test per ISO 10993-11, Biological Evaluation of medical devices, Part 11: Test for systemic toxicity. Under the conditions of the study, there was no mortality or evidence of acute systemic toxicity.	PASS
ISO 10993-11:2017	Biocompatibility: Material-Mediated Pyrogenicity	Passes Material-Mediated Pyrogenicity Test per ISO 10993-11, Biological Evaluation of medical devices, Part 11: Test for systemic toxicity. Under the conditions of the study, no pyrogenic response was observed.	PASS
USP <85>	Endotoxin Testing	Meets acceptance criteria for bacterial endotoxins per USP <85> Bacterial Endotoxins Test. Endotoxin level ≤ 20 EU/device.	PASS

Clinical Studies

A clinical study was not conducted in support of this submission.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K160781.