



August 30, 2022

Hong Seng Gloves SDN BHD  
% Michael Van Der Woude  
U.S. Agent  
Emergo Global Representative LLC  
2500 Bee Cave Road, Building 1 Suite 300  
Austin, Texas 78746

Re: K221164

Trade/Device Name: Powder Free Nitrile Examination Glove - Blue, Non-Sterile, Tested for use with  
Chemotherapy Drugs and Fentanyl  
Regulation Number: 21 CFR 880.6250  
Regulation Name: Non-Powdered Patient Examination Glove  
Regulatory Class: Class I, reserved  
Product Code: LZA, LZC, OPJ, QDO  
Dated: April 15, 2022  
Received: April 22, 2022

Dear Michael Van Der Woude:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bifeng Qian, M.D., Ph.D.  
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)

K221164

Device Name

POWDER FREE NITRILE EXAMINATION GLOVE - Blue, NON STERILE, TESTED FOR USE WITH CHEMOTHERAPY DRUGS AND FENTANYL

Indications for Use (Describe)

A Nitrile examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. These specialty gloves were tested for use with Chemotherapy drugs and Fentanyl.

Chemotherapy Drug	Breakthrough Detection Time in Minutes
*Carmustine (BCNU)	21.6
Cisplatin	> 240
Cyclophosphamide (Cytosan)	> 240
Dacarbazine	> 240
Doxorubicin HCl	> 240
Etoposide	> 240
Fluorouracil	> 240
Ifosfamide	> 240
Methotrexate	> 240
Mitomycin C	> 240
Mitoxantrone	> 240
Paclitaxel	> 240
*Thiotepa	81.3
Vincristine Sulfate	> 240
Fentanyl Citrate	> 240

\*Please note that the following drugs have extremely low permeation times: Carmustine: 21.6 minutes, Thio Tapa: 81.3 minutes.

Warning: Do not use with Carmustine and Thio Tapa

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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