August 18, 2023

Sentienx Sdn Bhd
% David Lim
Executive Director
TG Medical USA (INC)
165 N. Aspen Ave.
Azusa, California 91702

Re: K222993
Trade/Device Name: Flexylon Surgical Powder Free Gloves with Low Dermatitis Potential Claim, Green Tested For Use with 13 Chemotherapy Drugs; Flexylon Surgical Powder Free Gloves with Low Dermatitis Potential Claim, White Tested For Use with 32 Chemotherapy Drugs
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO, LZC, OPJ
Dated: August 15, 2023
Received: August 15, 2023

Dear David Lim:

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,

Bifeng Qian -S

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

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)*
K222993

Device Name
Flexylon Surgical Powder Free Gloves with Low Dermatitis Potential Claim, Green Tested For Use with 13 Chemotherapy Drugs

Indications for Use *(Describe)*
A powder-free surgeon's glove is a device made of synthetic elastomer that is intended to be worn by operating room personnel to protect a surgical wound from contamination. 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 and ASTM D6355-07, Standard Test Method for Human Repeat Insult Patch Testing of Medical Gloves.

Chemotherapy Drugs Permeation
The following drugs have been tested with these gloves

No.	Chemotherapy Drugs	Concentration	Breakthrough Detection Time in Minutes
1.	Carmustine	3.3 mg/ml	7.7
2.	Cisplatin	1.0 mg/ml	>240
3.	Cyclophosphamide	20.0 mg/ml	>240
4.	Dacarbazine	10.0 mg/ml	>240
5.	Doxorubicin HCI	2.0 mg/ml	>240
6.	Etoposide	20.0 mg/ml	>240
7.	Fluorouracil	50.0 mg/ml	>240
8.	Ifosfamide	50.0 mg/ml	>240
9.	Methotrexate	25.0 mg/ml	>240
10.	Mitomycin C	0.5 mg/ml	>240
11.	Paclitaxel (Taxol)	6.0 mg/ml	>240
12.	Thiotepa	10.0 mg/ml	11.4
13.	Vincristine Sulfate	1.0 mg/ml	>240

Warning: The permeation times for Carmustine and Thiotepa are extremely low with permeation times of 7.7 minutes and 11.4 minutes respectively. Do not use with Carmustine or 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.

Indications for Use

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

510(k) Number *(if known)*
K222993

Device Name
Flexylon Surgical Powder Free Gloves with Low Dermatitis Potential Claim, White Tested For Use with 32 Chemotherapy Drugs

Indications for Use *(Describe)*
A powder-free surgeon's glove is a device made of synthetic elastomer that is intended to be worn by operating room personnel to protect a surgical wound from contamination. 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 and ASTM D6355-07, Standard Test Method for Human Repeat Insult Patch Testing of Medical Gloves.

Chemotherapy Drugs Permeation

The following drugs have been tested with these gloves

No.	Chemotherapy Drugs	Concentration	Breakthrough Detection Time in Minutes
1.	Carmustine	3.3 mg/ml	11.9
2.	Cisplatin	1.0 mg/ml	>240
3.	Cyclophosphamide	20.0 mg/ml	>240
4.	Dacarbazine	10.0 mg/ml	>240
5.	Doxorubicin HCI	2.0 mg/ml	>240
6.	Etoposide	20.0 mg/ml	>240
7.	Fluorouracil	50.0 mg/ml	>240
8.	Ifosfamide	50.0 mg/ml	>240
9.	Methotrexate	25.0 mg/ml	>240
10.	Mitomycin C	0.5 mg/ml	>240
11.	Paclitaxel (Taxol)	6.0 mg/ml	>240
12.	Thiotepa	10.0 mg/ml	12.3
13.	Vincristine Sulfate	1.0 mg/ml	>240
14.	Bleomycin Sulfate	15.0 mg/ml	>240
15.	Busulfan	6.0 mg/ml	>240
16.	Carboplatin	10.0 mg/ml	>240
17.	Cytarabine HCI	100.0 mg/ml	>240
18.	Cytovene	10.0 mg/ml	>240
19.	Daunorubicin HCI	5.0 mg/ml	>240
20.	Docetaxel	10.0 mg/ml	>240
21.	Epirubicin HCI	2.0 mg/ml	>240
22.	Fludarabine	25.0 mg/ml	>240
23.	Gemcitabine (Gemzar)	38.0 mg/ml	>240
24.	Idarubicin HCI	1.0 mg/ml	>240
25.	Irinotecan	20.0 mg/ml	>240
26.	Mechlorethamine HCI	1.0 mg/ml	>240
27.	Melphalan	5.0 mg/ml	>240
28.	Mitoxantrone	2.0 mg/ml	>240
29.	Oxaliplatin	5.0 mg/ml	>240
30.	Rituximab	10.0 mg/ml	>240
31.	Trisenox	1.0 mg/ml	>240
32.	Vinorelbine	10.0 mg/ml	>240

Warning : The permeation times for Carmustine and Thiotepa are extremely low with permeation times of 11.9 minutes and 12.3 minutes respectively. Do not use with Carmustine or 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."