April 9, 2018

Lucenxia Prescience AG
Robert Hill
Regulatory Director
Rathausstrasse 7
Baar, CH6341, Switzerland

Re: K173386
Trade/Device Name: Finessis Zero Flexylon Powder Free Sterile White Surgical Gloves, Tested for use with Chemotherapy Drugs
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: Class I
Product Code: KGO, LZC
Dated: March 1, 2018
Received: March 5, 2018

Dear Robert Hill:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,
Geeta K. Pamidimukkala
-S
for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173386

Device Name
Finessis Zero Flexylon Powder Free Sterile White Surgical gloves
Tested for use with Chemotherapy Drugs

Indications for Use *(Describe)*
This surgeon's glove is a device made of Flexylon intended to be worn by operating room personnel to protect a surgical wound from contamination.

These Gloves are tested for use with Chemotherapy Drugs
DO NOT USE with Carmustine or Thiotepa.

	Tested Chemotherapy Drug and Concentration per ASTM D6978-05	Minimum BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)
1	Carmustine (BCNU), 3.3mg/ml (3,300 ppm)	6.9 (9.0, 12.3, 6.9)
2	Cisplatin, 1.0 mg/ml (1,000 ppm)	No Breakthrough up to 240 min.
3	Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	No Breakthrough up to 240 min.
4	Dacarbazine (DTIC) 10.0 mg/ml (10,000 ppm)	No Breakthrough up to 240 min.
5	Doxorubicin Hydrochloride, 2.0mg/ml (2,000 ppm)	No Breakthrough up to 240 min.
6	Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	No Breakthrough up to 240 min.
7	Fluorouracil, 50.0 mg/ml (50,000 ppm)	No Breakthrough up to 240 min.
8	Ifosfamide, 50.0 mg/ml (50,000 ppm)	No Breakthrough up to 240 min.
9	Methotrexate, 25 mg/ml (25,000 ppm)	No Breakthrough up to 240 min.
10	Mitomycin C, 0.5 mg/ml (500 ppm)	No Breakthrough up to 240 min.
11	Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	No Breakthrough up to 240 min.
12	Thiotepa, 10.0 mg/ml (10,000 ppm)	7.6 (9.2, 7.6, 10.0)
13	Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	No Breakthrough up to 240 min.
14	Bleomycin, 15 mg/ml (15,000 ppm)	No Breakthrough up to 240 min.
15	Busulfan, 6 mg/ml (6,000 ppm)	No Breakthrough up to 240 min.
16	Carboplatin, 10 mg/ml (10,000 ppm)	No Breakthrough up to 240 min.
17	Cytarabine, 100 mg/ml (100,000 ppm)	No Breakthrough up to 240 min.
18	Daunorubicin, 5 mg/ml (5,000 ppm)	No Breakthrough up to 240 min.
19	Docetaxel, 10.0 mg/ml (10,000 ppm)	No Breakthrough up to 240 min.
20	Epirubicin, 2.0 mg/ml (2,000 ppm)	No Breakthrough up to 240 min.
21	Fludarabine, 25 mg/ml (25,000 ppm)	No Breakthrough up to 240 min.
22	Ganciclovir, 10 mg/ml (10,000 ppm)	No Breakthrough up to 240 min.
23	Gemcitabine (Gemzar), 38 mg/ml (38,000 ppm)	No Breakthrough up to 240 min.
24	Idarubicin, 1.0 mg/ml (1,000 ppm)	No Breakthrough up to 240 min.
25	Irinotecan, 20.0 mg/ml (20,000 ppm)	No Breakthrough up to 240 min.
26	Mechlorethamine HCI, 1.0 mg/ml (1,000 ppm)	No Breakthrough up to 240 min.
27	Melphalan, 5.0 mg/ml (5,000 ppm)	No Breakthrough up to 240 min.
28	Mitoxantrone, 2.0 mg/ml (2,000 ppm)	No Breakthrough up to 240 min.
29	Oxaliplatin, 2.0 mg/ml (2,000 ppm)	No Breakthrough up to 240 min.
30	Rituximab, 10 mg/ml (10,000 ppm)	No Breakthrough up to 240 min.
31	Trisenox, 0.1 mg/ml (100 ppm)	No Breakthrough up to 240 min.
32	Vinorelbine, 10 mg/ml (10,000 ppm)	No Breakthrough up to 240 min.

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."