September 26, 2021

Cardinal Health 200, LLC
Padmini Sahoo
Regulatory Affairs Manager
3651 Birchwood Drive
Waukegan, Illinois 60085

Re: K201592
Trade/Device Name: Cardinal Health Protexis PI Blue with Neu-Thera Surgical Glove
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO, LZC
Dated: August 25, 2021
Received: August 26, 2021

Dear Padmini Sahoo:

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 Clarence W. Murray, III, PhD
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: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201592

Device Name

Cardinal Health™ Protexis™ PI Blue with Neu-Thera™ Surgical Gloves

Indications for Use *(Describe)*

Cardinal Health™ Protexis™ PI Blue with Neu-Thera™ Surgical Gloves are powder-free surgeon's gloves that are disposable devices made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.
In addition, these gloves have been tested for resistance to permeation of various chemotherapy drugs per ASTM D6978, "Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs."
Chemotherapy Drug Permeation Resistance (minimum breakthrough detection time in minutes, 0.01 μg/cm^2/min):

Carmustine	(3.3 mg/mL)	18.5
Cisplatin	(1 mg/mL)	>240
Cyclophosphamide	(20 mg/mL)	>240
Doxorubicin Hydrochloride	(2 mg/mL)	>240
Etoposide	(20 mg/mL)	>240
5-Fluorouracil	(50 mg/mL)	>240
Methotrexate	(25 mg/mL)	>240
Mitomycin C	(0.5 mg/mL)	>240
Paclitaxel	(6 mg/mL)	>240
Thiotepa	(10 mg/mL)	24.4
Vincristine Sulfate	(1 mg/mL)	>240

Please note that the gloves showed extremely low permeation times of 18.5 and 24.4 minutes respectively with Carmustine (BCNU) (3.3 mg/mL) and Thiotepa (10 mg/mL). When chemotherapy drugs are present, gloves selection should be based on the specific type(s) of chemicals used. Users are recommended to review drug labeling or material safety data sheets for the chemicals being used to determine an adequate level of protection.

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

Prescription Use (Part 21 CFR 801 Subpart D) X 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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