July 29, 2020

Cardinal Health 200, LLC
Caroline Miceli
Regulatory Affairs Manager
3651 Birchwood Drive
Waukegan, Illinois 60085

Re: K200824
Trade/Device Name: Cardinal Health SMARTGOWN Breathable Surgical Gown, Cardinal Health SMARTGOWN AIR Breathable Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: June 10, 2020
Received: June 12, 2020

Dear Ms. Miceli:

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 Elizabeth Claverie
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)*
K200824

Device Name
Cardinal Health™ SMARTGOWN™ Breathable Surgical Gown
Cardinal Health™ SMARTGOWN™ AIR Breathable Surgical Gown

Indications for Use *(Describe)*
Cardinal Health™ SMARTGOWN™ Breathable Surgical Gown and Cardinal Health™ SMARTGOWN™ AIR Breathable Surgical Gown are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. The gowns meet the barrier protection requirements of AAMI Level 4 per AAMI PB70:2012 Liquid Barrier and Performance Classification of Protective Apparel and Surgical Drapes Intended for Use in Health Care Facilities. The Cardinal Health™ SMARTGOWN™ Breathable Surgical Gown and Cardinal Health™ SMARTGOWN™ AIR Breathable Surgical Gown are single use, disposable medical devices provided sterile and non-sterile.

SMARTGOWN™ Breathable Surgical Gowns

Sterile	BNS	Case NS	Description
89005	89005N	N/A	Small/medium
89015	89015NA	N/A	Large
89045	89045NA	K89045N	X-large
89075	89075NA	K89075NA	XX-large
89085	89085N	N/A	XXX-large
89095	89095N	N/A	XXXX-large

SMARTGOWN™ Breathable Surgical Gowns with raglan sleeves

Sterile	BNS	Case NS	Description
39015	39015NA	K39015N	Large
39019	39019N	N/A	Large, X-long
39045	39045NA	N/A	X-large
39049	39049NA	K39049N	X-large, X-long
39075	39075NB	N/A	XX-large
39079	39079NB	N/A	XX-large, X-long
39099	39099NA	N/A	XXX-large, X-long
32474	32474NA	N/A	X-large, X-long, A-line
C32474	N/A	N/A	X-large, X-long, A-line

SMARTGOWN™ Breathable Scrub Nurse Gowns

Sterile	BNS	Case NS	Description
N/A	324740NA	N/A	X-large, X-long, A-line
N/A	890015NA	N/A	Large
N/A	890045NA	N/A	X-large

SMARTGOWN™ AIR Breathable Surgical Gowns

Sterile	BNS	Description
29005	29005N	Small/medium
29015	29015N	Large
29019	29019N	Large, X-long
29045	29045N	X-large
29049	29049N	X-large, X-long
29075	29075N	XX-large
29079	29079N	XX-large, X-long
29085	29085N	XXX-large
29089	29089N	XXX-large, X-long
29095	29095N	XXXX-large
29099	29099N	XXXX-large, X-long

SMARTGOWN™ AIR Breathable Scrub Nurse Gowns

Sterile	BNS	Description
N/A	290015N	Large
N/A	290045N	X-large

BNS = Bulk Non-Sterile
Case NS = Case Non-Sterile

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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