March 20, 2020

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

Re: K193327
Trade/Device Name: Cardinal Health ChemoPlus Full Coverage Gown, Closed Back, Cardinal Health ChemoPlus Full Coverage Gown, Open Back
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: January 28, 2020
Received: January 29, 2020

Dear Caroline 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,

Elizabeth F. Claverie, MS
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

Form Approved: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193327

Device Name

Cardinal Health™ ChemoPlus™ Full Coverage Gown, Closed Back
Cardinal Health™ ChemoPlus™ Full Coverage Gown, Open Back

Indications for Use *(Describe)*

Cardinal Health™ ChemoPlus™ Full Coverage Gown, Closed Back

The Cardinal Health™ ChemoPlus™ Full Coverage Gowns, Closed Back, are intended to protect healthcare personnel from exposure to chemotherapy drugs during preparation, handling, and administration.

The closed back gowns are single use, disposable medical devices provided sterile and non-sterile. The non-sterile, closed back gowns are not intended for use in the operating room.

ChemoPlus™ Gowns Catalog Number Summary

Catalog Number	Product Description	Size	Sterility
CT5502T	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	M	Non-sterile
CT5503T	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	L	Non-sterile
CT5504T	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	XL	Non-sterile
CT5505T	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	XXL	Non-sterile
CT5502TS	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	M	Sterile
CT5503TS	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	L	Sterile
CT5504TS	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	XL	Sterile
CT5505TS	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	XXL	Sterile

The proposed gowns meet the barrier protection requirements of AAMI Level 3 per ANSI/AAMI Standard PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes intended for use in Health Care Facilities.

The gowns have been evaluated for resistance to permeation of various chemotherapy drugs per ASTM F739-12, Standard Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact. Chemotherapy drug permeation resistance, average standardized breakthrough time in minutes*:

Carmustine [3.3 mg/ml] >480
Cisplatin [1.0 mg/ml] >480
Cyclophosphamide [20 mg/ml] >480
Cytarabine Hydrochloride [100 mg/ml] >480
Dacarbazine [10 mg/ml] >480
Daunorubicin Hydrochloride [5 mg/ml] >480
Doxorubicin Hydrochloride [2 mg/ml] > 480
Etopside [20 mg/ml] >480
Fluorouracil [50 mg/ml] >480
lfosfamide [50 mg/ml] > 480
Methotrexate [25 mg/ml] >480
Mitomycin C [0.5 mg/ml] >480
Mitoxantrone [2.0 mg/ml] >480

Paclitaxel [6 mg/ml] >480
Thiotepa [10 mg/ml] >480
Vincristine Sulfate [1 mg/ml] >480

*No permeation was detected at either the minimum detectable permeation or 0.1 μg/cm^2/min

When chemotherapy drugs are present, gown 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.

Cardinal Health™ ChemoPlus™ Full Coverage Gown, Open Back

The Cardinal Health™ ChemoPlus™ Full Coverage Gowns, Open Back, are intended to protect healthcare personnel from exposure to chemotherapy drugs during preparation, handling, and administration.

The open back gowns are single use, disposable medical devices provided non-sterile. The open-back gown is non-protective in the back. The open-back gowns are not intended for use in the operating room.

ChemoPlus™ Gowns Catalog Number Summary

Catalog Number	Product Description	Size	Sterility
DP5003GT	Cardinal Health™ ChemoPlus™ Full Coverage Gown Open Back	M	Non-Sterile
DP5001GT	Cardinal Health™ ChemoPlus™ Full Coverage Gown Open Back	L	Non-Sterile
DP5002GT	Cardinal Health™ ChemoPlus™ Full Coverage Gown Open Back	XL	Non-Sterile
DP5004GT	Cardinal Health™ ChemoPlus™ Full Coverage Gown Open Back	XXL	Non-Sterile

The proposed gowns meet the barrier protection requirements of AAMI Level 3 per ANSI/AAMI Standard PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes intended for use in Health Care Facilities.

The gowns have been evaluated for resistance to permeation of various chemotherapy drugs per ASTM F739-12, Standard Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact. Chemotherapy drug permeation resistance, average standardized breakthrough time in minutes*:

Carmustine [3.3 mg/ml] >480
Cisplatin [1.0 mg/ml] >480
Cyclophosphamide [20 mg/ml] >480
Cytarabine Hydrochloride [100 mg/ml] >480
Dacarbazine [10 mg/ml] >480
Daunorubicin Hydrochloride [5 mg/ml] >480
Doxorubicin Hydrochloride [2 mg/ml] > 480
Etopside [20 mg/ml] >480
Fluorouracil [50 mg/ml] >480
lfosfamide [50 mg/ml] > 480
Methotrexate [25 mg/ml] >480
Mitomycin C [0.5 mg/ml] >480
Mitoxantrone [2.0 mg/ml] >480

Paclitaxel [6 mg/ml] >480
Thiotepa [10 mg/ml] >480
Vincristine Sulfate [1 mg/ml] >480

*No permeation was detected at either the minimum detectable permeation or 0.1 $\mu g/cm^2/min$

When chemotherapy drugs are present, gown 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.

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3651 Birchwood Drive
Waukegan, IL 60085
www.cardinalhealth.com

510(k) SUMMARY K193327
Cardinal Health™ ChemoPlus™ Full Coverage Gown, Closed Back
Cardinal Health™ ChemoPlus™ Full Coverage Gown, Open Back

Manufacturer:	Cardinal Health 200, LLC 3651 Birchwood Drive Waukegan, IL 60085
Regulatory Affairs Contact:	Caroline Miceli 3651 Birchwood Drive Waukegan, IL 60085
Telephone Number:	(312) 270-2013
Fax Number:	847-473-2114
Date Summary Prepared:	March 18, 2020
Trade Name:	Cardinal Health™ ChemoPlus™ Full Coverage Gown, Closed Back Cardinal Health™ ChemoPlus™ Full Coverage Gown, Open Back
Regulation Number:	21 CFR §878.4040
Device Class:	Class II
Regulation Name:	Surgical Apparel
Common/Classification Name:	Surgical Gown
Product Codes:	FYA
Predicate Device:	Kimberly-Clark Procedure Gown (K052824)

Description

The Cardinal Health™ ChemoPlus™ Full Coverage Closed Back and Open Back Gowns are classified as Class II medical devices under Regulation 21 CFR 878.4040, General & Plastic Surgery Panel, FDA product code FYA, Surgical Gown.

The device description of the Cardinal Health™ ChemoPlus™ Gowns is in accordance with the *Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes*, issued on August 1, 1993 and *Guidance for Industry and FDA Staff: Premarket Notification Requirements Concerning Gowns Intended for Use in Healthcare Settings*, issued on December 9, 2015.

The ChemoPlus™ Full Coverage Closed Back and Open Back Gowns are made of a laminate with adhesive taped seams. Both closed and open back gowns have a hook and loop closure at the back of the neck and a waist tie feature to secure the gown to the body of the user. The sleeves of the gown have knit cuffs sewn onto the end of the sleeve at the user's wrists to keep the sleeves in place on the wearer. The entire gown including the gown sleeves are made of the same material and utilize the same manufacturing processes.

ChemoPlus™ Gowns Catalog Number Summary

Catalog Number	Product Description	Size	Sterility
CT5502T	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	M	Non-sterile
CT5503T	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	L	Non-sterile
CT5504T	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	XL	Non-sterile
CT5505T	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	XXL	Non-sterile
CT5502TS	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	M	Sterile
CT5503TS	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	L	Sterile
CT5504TS	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	XL	Sterile
CT5505TS	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	XXL	Sterile
DP5003GT	Cardinal Health™ ChemoPlus™ Full Coverage Gown Open Back	M	Non-Sterile
DP5001GT	Cardinal Health™ ChemoPlus™ Full Coverage Gown Open Back	L	Non-Sterile
DP5002GT	Cardinal Health™ ChemoPlus™ Full Coverage Gown Open Back	XL	Non-Sterile
DP5004GT	Cardinal Health™ ChemoPlus™ Full Coverage Gown Open Back	XXL	Non-Sterile

Indications for Use

The Cardinal Health™ ChemoPlus™ Full Coverage Gowns, Closed Back, are intended to protect healthcare personnel from exposure to chemotherapy drugs during preparation, handling, and administration. The closed back gowns are single use, disposable medical devices provided sterile and non- sterile. The non-sterile, closed back gowns are not intended for use in the operating room.

The Cardinal Health™ ChemoPlus™ Full Coverage Gowns, Open Back, are intended to protect healthcare personnel from exposure to chemotherapy drugs during preparation, handling, and administration. The open back gowns are single use, disposable medical devices provided non-sterile. The open back gown is nonprotective in the back. The open back gowns are not intended for use in the operating room.

ChemoPlus™ Gowns Catalog Number Summary

Catalog Number	Product Description	Size	Sterility
CT5502T	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	M	Non-sterile
CT5503T	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	L	Non-sterile
CT5504T	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	XL	Non-sterile
CT5505T	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	XXL	Non-sterile
CT5502TS	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	M	Sterile
CT5503TS	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	L	Sterile
CT5504TS	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	XL	Sterile
CT5505TS	Cardinal Health™ ChemoPlus™ Full Coverage Gown Closed Back	XXL	Sterile
DP5003GT	Cardinal Health™ ChemoPlus™ Full Coverage Gown Open Back	M	Non-Sterile
DP5001GT	Cardinal Health™ ChemoPlus™ Full Coverage Gown Open Back	L	Non-Sterile
DP5002GT	Cardinal Health™ ChemoPlus™ Full Coverage Gown Open Back	XL	Non-Sterile
DP5004GT	Cardinal Health™ ChemoPlus™ Full Coverage Gown Open Back	XXL	Non-Sterile

The proposed gowns meet the barrier protection requirements of AAMI Level 3 per ANSI/AAMI Standard PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities.

The gowns have been evaluated for resistance to permeation of various chemotherapy drugs per ASTM F739-12, *Standard Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact*.

Chemotherapy drug permeation resistance, average standardized breakthrough time in minutes *:

Carmustine [3.3 mg/ml] >480
Cisplatin [1.0 mg/ml] >480
Cyclophosphamide [20 mg/ml] >480
Cytarabine Hydrochloride [100 mg/ml] >480
Dacarbazine [10 mg/ml] >480
Daunorubicin Hydrochloride [5 mg/ml] >480
Doxorubicin Hydrochloride [2 mg/ml] >480
Etopside [20 mg/ml] >480
Fluorouracil [50 mg/ml] >480
Ifosfamide [50 mg/ml] >480
Methotrexate [25 mg/ml] >480
Mitomycin C [0.5 mg/ml] >480
Mitoxantrone [2.0 mg/ml] >480
Paclitaxel [6 mg/ml] >480
Thiotepa [10 mg/ml] >480
Vincristine Sulfate [1 mg/ml] >480

*No permeation was detected at either the minimum detectable permeation or 0.1 μg/cm²/min

When chemotherapy drugs are present, gown 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.

Technological Characteristics Comparison Tables

Shown below is the technological characteristics comparison of the subject or proposed device and the predicate device. Refer to Table 1 and Table 2.

Table 1: Cardinal Health™ ChemoPlus™ Full Coverage Gowns, Closed Back

Element of Comparison	**Predicate Device:** K052824 Kimberly-Clark Procedure Gown	**Proposed Device:** K193327 Cardinal Health™ ChemoPlus™ Full Coverage Gowns, Closed Back	**Comparison:**
Intended Use	The Kimberly-Clark Procedure Gown is a non-sterile, disposable, single use item of apparel intended to be worn by healthcare professionals during the preparation and administration of selected chemotherapy drugs. The gown is not intended to be worn during surgical procedures.	The Cardinal Health™ ChemoPlus™ Full Coverage Gowns, Closed Back, are intended to protect healthcare personnel from exposure to chemotherapy drugs during preparation, handling, and administration. The closed back gowns are single use, disposable medical devices provided sterile and non-sterile. The non-sterile, closed back gowns are not intended for use in the operating room.	Similar
Indications for Use	Not available in the predicate device 510(k) Summary	The proposed gowns meet the barrier protection requirements of AAMI Level 3 per ANSI/AAMI Standard PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes intended for use in Health Care Facilities. The gowns have been evaluated for resistance to permeation of various chemotherapy drugs per ASTM F739-12, Standard Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact. Chemotherapy drug permeation resistance, average standardized breakthrough time in minutes *: Carmustine [3.3 mg/ml] >480 Cisplatin [1.0 mg/ml] >480 Cyclophosphamide [20 mg/ml] >480 Cytarabine Hydrochloride [100 mg/ml] >480 Dacarbazine [10 mg/ml] >480 Daunorubicin Hydrochloride [5 mg/ml] >480 Doxorubicin Hydrochloride [2 mg/ml] >480 Etopside [20 mg/ml] >480	Similar

Element of Comparison	**Predicate Device:** K052824 Kimberly-Clark Procedure Gown	**Proposed Device:** K193327 Cardinal Health™ ChemoPlus™ Full Coverage Gowns, Closed Back	**Comparison:**
		Fluorouracil [50 mg/ml] >480 Ifosfamide [50 mg/ml] >480 Methotrexate [25 mg/ml] >480 Mitomycin C [0.5 mg/ml] >480 Mitoxantrone [2.0 mg/ml] >480 Paclitaxel [6 mg/ml] >480 Thiotepa [10 mg/ml] >480 Vincristine Sulfate [1 mg/ml] >480 *No permeation was detected at either the minimum detectable permeation or 0.1 µg/cm²/min When chemotherapy drugs are present, gown selection should be based on the specific type(s) of chemicals used. Users are recommended to review drug labeling or material safety data sheets of the chemicals being used to determine an adequate level of protection.	
Directions for Use	None	None	Same
Material Composition	Nonwoven polypropylene spunbond fabric with a polyethylene laminate coating.	Nonwoven polypropylene spunbond fabric with a polyethylene laminate coating (also referred to as laminate)	Similar
Design Features	Knit Cuff Tape-Tab Neck Closure Belt Ties	Polyester Knit cuff Hook and Loop Neck Closure Belt Ties integrated in the back of gown Taped seams	Similar
Sterility	Non-sterile	Sterile and Non-sterile	Similar
Use	Single Use; Disposable	Single Use; Disposable	Same
Color	Blue	Blue	Similar
Gown Style	Open Back	Closed Back	Similar

Table 2: Cardinal Health™ ChemoPlus™ Full Coverage Gowns, Open Back

Element of Comparison	**Predicate Device:** K052824 Kimberly-Clark Procedure Gown	**Proposed Device:** K193327 Cardinal Health™ ChemoPlus™ Full Coverage Gowns, Open Back	**Comparison:**
Intended Use	The Kimberly-Clark Procedure Gown is a non-sterile, disposable, single use item of apparel intended to be worn by healthcare professionals during the preparation and administration of selected chemotherapy drugs. The gown is not intended to be worn during surgical procedures.	The Cardinal Health™ ChemoPlus™ Full Coverage Gowns, Open Back, are intended to protect healthcare personnel from exposure to chemotherapy drugs during preparation, handling, and administration. The open back gowns are single use, disposable medical devices provided non-sterile. The open back gown is nonprotective in the back. The open back gowns are not intended for use in the operating room.	Similar
Indications for Use	Not available in the predicate device 510(k) Summary	The proposed gowns meet the barrier protection requirements of AAMI Level 3 per ANSI/AAMI Standard PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes intended for use in Health Care Facilities. The gowns have been evaluated for resistance to permeation of various chemotherapy drugs per ASTM F739-12, Standard Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact. Chemotherapy drug permeation resistance, average standardized breakthrough time in minutes *: Carmustine [3.3 mg/ml] >480 Cisplatin [1.0 mg/ml] >480 Cyclophosphamide [20 mg/ml] >480 Cytarabine Hydrochloride [100 mg/ml] >480 Dacarbazine [10 mg/ml] >480 Daunorubicin Hydrochloride [5 mg/ml] >480 Doxorubicin Hydrochloride [2 mg/ml] >480 Etopside [20 mg/ml] >480 Fluorouracil [50 mg/ml] >480 Ifosfamide [50 mg/ml] >480 Methotrexate [25 mg/ml] >480 Mitomycin C [0.5 mg/ml] >480 Mitoxantrone [2.0 mg/ml] >480 Paclitaxel [6 mg/ml] >480 Thiotepa [10 mg/ml] >480 Vincristine Sulfate [1 mg/ml] >480	Similar

Element of Comparison	**Predicate Device:** K052824 Kimberly-Clark Procedure Gown	**Proposed Device:** K193327 Cardinal Health™ ChemoPlus™ Full Coverage Gowns, Open Back	**Comparison:**
		*No permeation was detected at either the minimum detectable permeation or 0.1 µg/cm²/min When chemotherapy drugs are present, gown selection should be based on the specific type(s) of chemicals used. Users are recommended to review drug labeling or material safety data sheets of the chemicals being used to determine an adequate level of protection.	
Directions for Use	None	None	Same
Material Composition	Nonwoven polypropylene spunbond fabric with a polyethylene laminate coating.	Nonwoven polypropylene spunbond fabric with a polyethylene laminate coating (also referred to as laminate)	Similar
Design Features	Knit Cuff Tape-Tab Neck Closure Belt Ties	Polyester Knit cuff Hook and Loop Neck Closure Belt Ties integrated in the back of gown Taped seams	Similar
Sterility	Non-sterile	Non-sterile	Same
Use	Single Use; Disposable	Single Use; Disposable	Same
Color	Blue	Blue	Similar
Gown Style	Open Back	Open Back	Same

Non-Clinical Performance Testing

Test results establish that the proposed devices meet acceptance criteria for its intended use and demonstrate that each device is as safe and as effective as the predicate device.

Refer to the Summary of Non-Clinical Performance Testing, Table 1 and Table 2 below. The tables include a summary of the non-clinical performance testing and followed by a comparison of the predicate and proposed devices.

Summary of Non-Clinical Performance Testing

Table 1: Cardinal Health™ ChemoPlus™ Full Coverage Gowns, Closed Back

Standards	Purpose	Acceptance Criteria	Results
AATCC 42	Spray Impact	Water Resistance	PASS
AATCC 127	Hydrostatic Pressure	Water Resistance	PASS
ANSI/AAMI PB70:2012 AAMI Level 3	Liquid Barrier Performance	Water Resistance	PASS
ASTM F739-12	Permeation of Liquids and Gasses through Protective Clothing	Chemical Permeation Under Continuous Contact	PASS
ASTM D3776/D3776M-17	Weight of Woven Fabric	Material Weight	PASS
ASTM D5034 – 9 2017	Grab Tensile, Peak Stretch, and Peak Energy – Nonwovens	Tensile Strength	PASS
ASTM 1683-17 (2018)	Standard Test Method for Failure in Sewn Seams of Woven Apparel Fabrics	Seam Strength	PASS

ASTM D5587-15 (2019)	Standard Test Method for Tearing Strength of Fabrics by the Trapezoid Procedure	Trapezoid Tear	PASS
NWSP 160.1	Resistance to Linting of Nonwoven Fabrics (Dry)	Particulate	PASS
16 CFR 1610	Standard for the Flammability for Clothing Textiles	Flammability	PASS
ISO 10993-5:2009	ISO MEM Elution Cytotoxicity	Cytotoxicity	PASS
ISO 10993 10:2010	ISO Indirect Primary Skin Irritation Test	Irritation	PASS
ISO 10993-10:2010	Guinea Pig Maximization Test	Sensitization	PASS
ISO 10993-7:2008 (R) 2012	EO Sterilization Residuals (Sterile Catalog Numbers)	EO and ECH Residuals	PASS

Element of Comparison	**Predicate Device:** K052824 Kimberly-Clark Procedure Gown	**Proposed Device:** K193327 Cardinal Health™ ChemoPlus™ Full Coverage Gowns, Closed Back	**Comparison:**
Liquid Barrier Performance Classification Properties	Penetration testing per ASTM F1670-03 with resistance of the gown fabric to penetration by blood under conditions of continuous liquid contact. The 'pass' determination was based on visual detection of synthetic blood penetration. Penetration testing per ASTM F1671-03 with resistance of the gown fabric to penetration by blood borne pathogen under conditions of continuous liquid contact. The 'pass' determination was based on detection of viral penetration.	The proposed device meets the barrier protection requirements of AAMI Level 3 per *ANSI/AAMI PB70:2012, Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities.*	Different
Biocompatibility	Dermal Irritation and Sensitization: No evidence of dermal irritation or allergic contact sensitization.	Under the conditions of each study, the Cardinal Health™ ChemoPlus™ Full Coverage Gown, Closed Back is non-cytotoxic, non-irritating and non-sensitizing and have met the requirements per ISO-10993-1.	Similar
Liquid Chemical Permeation	Permeation testing per ASTM F739-99a with the following chemotherapy drugs: Carmustine, Cisplatin, Cyclophosphamide, dacarbazine, doxorubicin hydrochloride, etoposide, fluorouracil, paclitaxel, Thiotepa, and vincristine sulfate. Results showed no permeation of the drugs for up to 240 minutes.	These proposed gowns have been evaluated for the following chemotherapy drugs according to ASTM F739-12: Carmustine, Cisplatin, Cyclophosphamide, Cytarabine, Dacarbazine, Daunorubicin, Doxorubicin Hydrochloride, Etoposide, Fluorouracil, Ifosfamide, Methotrexate, Mitomycin C, Mitoxantrone, Paclitaxel, Thiotepa, Vincristine Sulfate. Results showed no average standardized breakthrough for up to 480 minutes.	Similar
Sterilization Modality	None, non-sterile	None, non-sterile Ethylene Oxide (EO) Sterilization for sterile catalog numbers.	Similar
Flammability	Meets Class I flammability requirements per NFPA Standard #702-1980**	Meet Class I Flammability per CPSC, Part 1610	Similar

**Flammability standard, NFPA 702-1980 is now an inactive standard. NFPA 702-1980 has since been replaced by CPSC Part 1610 to evaluate the flammability class of protective apparel.

Summary of Non-Clinical Performance Testing

Table 2: Cardinal Health™ ChemoPlus™ Full Coverage Gowns, Open Back

Standards	Purpose	Acceptance Criteria	Results
AATCC 42	Spray Impact	Water Resistance	PASS
AATCC 127	Hydrostatic Pressure	Water Resistance	PASS
ANSI/AAMI PB70:2012 AAMI Level 3	Liquid Barrier Performance	Water Resistance	PASS
ASTM F739-12	Permeation of Liquids and Gasses through Protective Clothing	Chemical Permeation Under Continuous Contact	PASS
ASTM D3776/D3776M-17	Weight of Woven Fabric	Material Weight	PASS
ASTM D5034 – 9 2017	Grab Tensile, Peak Stretch, and Peak Energy – Nonwovens	Tensile Strength	PASS
ASTM 1683-17 (2018)	Standard Test Method for Failure in Sewn Seams of Woven Apparel Fabrics	Seam Strength	PASS
ASTM D5587-15 (2019)	Standard Test Method for Tearing Strength of Fabrics by the Trapezoid Procedure	Trapezoid Tear	PASS
NWSP 160.1	Resistance to Linting of Nonwoven Fabrics (Dry)	Particulate	PASS

16 CFR 1610	Standard for the Flammability for Clothing Textiles	Flammability	PASS
ISO 10993-5:2009	ISO MEM Elution Cytotoxicity	Cytotoxicity	PASS
ISO 10993 10:2010	ISO Indirect Primary Skin Irritation Test	Irritation	PASS
ISO 10993-10:2010	Guinea Pig Maximization Test	Sensitization	PASS

Element of Comparison	**Predicate Device:** K052824 Kimberly-Clark Procedure Gown	**Proposed Device:** Cardinal Health™ ChemoPlus™ Full Coverage Gowns, Open Back	**Comparison:**
Liquid Barrier Performance Classification Properties	Penetration testing per ASTM F1670-03 with resistance of the gown fabric to penetration by blood under conditions of continuous liquid contact. The 'pass' determination was based on visual detection of synthetic blood penetration. Penetration testing per ASTM F1671-03 with resistance of the gown fabric to penetration by blood borne pathogen under conditions of continuous liquid contact. The 'pass' determination was based on detection of viral penetration.	The proposed device meets the barrier protection requirements of AAMI Level 3 per *ANSI/AAMI PB70:2012, Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities.* The ChemoPlus™ Full Coverage Open Back Gown has an open back which is non-protective.	Different
Biocompatibility	Dermal Irritation and Sensitization: No evidence of dermal irritation or allergic contact sensitization.	Under the conditions of each study, the Cardinal Health™ ChemoPlus™ Full Coverage Gown, Open Back is non-cytotoxic, non-irritating and non-sensitizing and have met the requirements per ISO-10993-1.	Similar
Liquid Chemical Permeation	Permeation testing per ASTM F739-99a with the following chemotherapy drugs: Carmustine, Cisplatin, Cyclophosphamide, dacarbazine, doxorubicin hydrochloride, etoposide, fluorouracil, paclitaxel, Thiotepa, and vincristine sulfate. Results showed no permeation of the drugs for up to 240 minutes.	These proposed gowns have been evaluated for the following chemotherapy drugs according to ASTM F739-12: Carmustine, Cisplatin, Cyclophosphamide, Cytarabine, Dacarbazine, Daunorubicin, Doxorubicin Hydrochloride, Etoposide, Fluorouracil, Ifosfamide, Methotrexate, Mitomycin C, Mitoxantrone, Paclitaxel, Thiotepa, Vincristine Sulfate. Results showed no average standardized breakthrough for up to 480 minutes.	Similar
Sterilization Modality	None, non-sterile	None, non-sterile	Same
Flammability	Meets Class I flammability requirements per NFPA Standard #702-1980**	Meet Class I Flammability per CPSC, Part 1610	Similar

**Flammability standard, NFPA 702-1980 is now an inactive standard. NFPA 702-1980 has since been replaced by CPSC Part 1610 to evaluate the flammability class of protective apparel.

The following standards were evaluated for the Cardinal Health™ ChemoPlus™ Full Coverage Gowns, both Open and Closed Back to further characterize these devices.

List of Standard Test Methods Performed

Standard Number	Standard Title
ANSI/AAMI PB70:2012	Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities.
ASTM D3776/D3776M-17	Test Methods for Mass Per Unit Area (Weight) of Woven Fabric
ASTM D5034-09 (2017)	Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)
ASTM 1683-17 (2018)	Standard Test Method for Failure in Sewn Seams of Woven Apparel Fabrics
ASTM D5587-15 (2019)	Standard Test Method for Tearing Strength of Fabrics by the Trapezoid Procedure
NWSP 160.1	Resistance to Linting of Nonwoven Fabrics (Dry)
AATCC 127-2017	Water Resistance: Hydrostatic Pressure Test
AATCC 42-2017	Water Resistance: Water Impact Test
16 CFR Part 1610	Standard for the Flammability of Clothing Textiles (2016)
ASTM F739-12	Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact
ISO 10993-5:2009	Biological Evaluation of Medical Devices- Part 5: Tests for In-Vitro Cytotoxicity
ISO 10993-10:2010	Biological Evaluation of Medical Devices- Part 10: Tests for irritation and delayed-type hypersensitivity
ISO 10993-7:2008 (R) 2012	EO Sterilization Residues, Section 4.3.3 – Limited Exposure Devices.

Conclusion

The Cardinal Health™ ChemoPlus™ Full Coverage Gown, Closed Back and the Cardinal Health™ ChemoPlus™ Full Coverage Gown, Open Back gowns are as safe, as effective and perform as well as or better than the legally marketed predicate device identified in this submission.