October 21, 2022

Medtecs (Taiwan) Corp.
℅ Sandy Liu
Consultant
Jin Services Co.
9F-1, No13, Lane41, Zhangrong Rd, Sec. 5, North District
Tainan City, 70447
Taiwan

Re: K210414
Trade/Device Name: CoverU Disposable Gown with Tape AAMI Level 4 Isolation Gown
CoverU Disposable Gown with Tape - Chemo Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYC, QSO
Dated: September 26, 2022
Received: September 26, 2022

Dear Sandy Liu:

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, 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)*
K210414

Device Name
CoverU Disposable Gown with Tape AAMI Level 4 Isolation Gown

Indications for Use *(Describe)*
CoverU Disposable Gown with Tape - AAMI Level 4 Isolation Gown (Model number: IL-4036YKTP-L4) is intended to provide barrier protection and protect healthcare personnel and patients from the transfer of microorganisms, body fluids and particulate material. CoverU Disposable Gown with Tape meets the requirements of AAMI Level 4 barrier protection for a surgical isolation gown per ANSI/ AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. Not intended for use in the operating room. CoverU Disposable Gown with Tapes is a single use, disposable medical device provided non-sterile.

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."

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)*
K210414

Device Name
CoverU Disposable Gown with Tape - Chemo Gown

Indications for Use *(Describe)*
CoverU Disposable Gown with Tape- Chemo Gown (Model number: IL-4036YKTP-CM) is intended to provide barrier protection and protect healthcare personnel and patients from the transfer of microorganisms, body fluids and particulate material. CoverU Disposable Gown with Tape meets the requirements of AAMI Level 4 barrier protection for a surgical isolation gown per ANSI/ AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. Not intended for use in the operating room. CoverU Disposable Gown with Tapes is a single use, disposable medical device provided non-sterile. 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
Docetaxel [10mg/ml] >480
Oxaliplatin [5mg/ml] >480
Leucovorin [10mg/ml] >480
*No permeation was detected at either the minimum detectable permeation or 0.1 μg/cm2/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."

510(k) Summary

510(k) Number: K210414

Applicant Information

Company Name: MEDTECS (TAIWAN) CORP.
Company Address: 11F., No. 9, Songgao Road
Xinyi Dist., 11073, Taiwan
Telephone: +886-2-27392222
Fax: +886-2-27297896
Submitter: William Yang

Summary Preparation Date: 2022.10.17

Official Correspondent

Company Name: Jin Services Co.
Company Address: 9F-1, No13, Lane41, Changrong Rd, Sec. 5,
North Distrit, Tainan City, 70447 Taiwan
Telephone: +886-917535026
Email: contact@fdaclass.com
Contact Person: Sandy Liu, Consultant

Device Name:

Trade Name: 1) CoverU Disposable Gown with Tape AAMI Level 4 Isolation Gown
2) CoverU Disposable Gown with Tape - Chemo Gown
Classification Name: Gown, Isolation, Surgical
Regulation Number: 878.4040
Product Code: FYC, QSO
Device Class: Class 2
Panel: General Hospital

PREDICATE DEVICE:

- K190306, AMD Ritmed AssureWear VersaGown - AMD Medicom Inc.

REFERENCE DEVICE:

- K193327, Cardinal Health ChemoPlus Full Coverage Gown, Closed Back - Cardinal Health 200, LLC,

Device Description

The CoverU Disposable Gown with Tape is constructed of PPSB Coated PE materials with the color in yellow. It is sealed the seam by Adheresive tape provide protection from liquid borne. 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. Tie at the neck and waist for secure protection AAMI level 4 standard provides high performance on hydrostatic pressure and fluids impact.
The CoverU Disposable Gown with Tape is sold in one size, non-sterile and is intended to be a single use, disposable device, and does NOT contain any drugs or biologics and not made with natural rubber latex. The two gown models are exact the same gowns, except the chemo-drug labeling claim. one is intended to protect workers from high fluid level (blood body fluids etc.) and blood borne pathogen, and the other is intended to protect healthcare personnel from exposure to chemotherapy drugs during preparation, handling, and administration. Ten (10) pieces of CoverU Disposable Gown

with Tape are packaged in a plastic bag and ten bags are outer packaging with a paper carton box. These gowns are offered in a universal size.

Intended Use/Indications for Use:

The CoverU Disposable Gown with Tape AAMI Level 4 Isolation Gown (Model number: IL4036YKTP-L4) is intended to provide barrier protection and protect healthcare personnel and patients from the transfer of microorganisms, body fluids and particulate material. CoverU Disposable Gown with Tape meets the requirements of AAMI Level 4 barrier protection for a surgical isolation gown per ANSI/ AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. Not intended for use in the operating room. CoverU Disposable Gown with Tapes is a single use, disposable medical device provided non-sterile.

The CoverU Disposable Gown with Tape - Chemo Gown (Model number IL-4036YKTP-CM) is intended to provide barrier protection and protect healthcare personnel and patients from the transfer of microorganisms, body fluids and particulate material. CoverU Disposable Gown with Tape meets the requirements of AAMI Level 4 barrier protection for a surgical isolation gown per ANSI/ AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. Not intended for use in the operating room. CoverU Disposable Gown with Tapes is a single use, disposable medical device provided non-sterile. 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
Docetaxel [10mg/ml] >480
Oxaliplatin [5mg/ml] >480
Leucovorin [10mg/ml] >480

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

Technological characteristics Comparison for the proposed and predicate devices

The following is a summary of the technological characteristics of the CoverU Disposable Gown with Tape as compared to the predicate device.

Items	Subject Device The CoverU Disposable Gown with Tape (K210414)	Predicate Device AMD Ritmed AssureWear VersaGown (K190306)	Comparison Result
Submitter	MEDTECS (TAIWAN) CORP.	Yanbian Pacific Textile Co., LTD	N/A
Device Regulation number	21 CFR 878.4040	21 CFR 878.4040	Same
Classification	2	2	Same
FDA Product Code	FYC	FYC	Same
Sub-model	AAMI Level 4 Isolation Gown (Model number: IL-4036YKTP-L4) and Chemo Gown (Model number IL-4036YKTP-CM)	No information on 510(k) summary	N/A
Indications for Use (CoverU Disposable Gown with Tape AAMI Level 4 Isolation Gown)	The CoverU Disposable Gown with Tape AAMI Level 4 Isolation Gown (Model number: IL4036YKTP-L4) is intended to provide barrier protection and protect healthcare personnel and patients from the transfer of microorganisms, body fluids and particulate material. CoverU Disposable Gown with Tape meets the requirements of AAMI Level 4 barrier protection for a surgical isolation gown per ANSI/ AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. Not intended for use in the operating room. CoverU Disposable Gown with Tapes is a single use, disposable medical device provided non-sterile	AMD Ritmed AssureWear™ VersaGown is intended to be worn by healthcare personnel to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. AssureWear™ VersaGown meets the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier Performance Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70). AMD Ritmed AssureWear™ Versa Gown is a single use, non-sterile disposable medical device and not intended for use in operating rooms. The medical device will be available in 18 models in large and Xlarge sizes.	Identical

Indications for Use (The CoverU Disposable Gown with Tape - Chemo Gown)	The CoverU Disposable Gown with Tape - Chemo Gown (Model number IL-4036YKTP-CM) is intended to provide barrier protection and protect healthcare personnel and patients from the transfer of microorganisms, body fluids and particulate material. CoverU Disposable Gown with Tape meets the requirements of AAMI Level 4 barrier protection for a surgical isolation gown per ANSI/ AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. Not intended for use in the operating room. CoverU Disposable Gown with Tapes is a single use, disposable medical device provided non-sterile 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	No related indication for use of "intended to protect healthcare personnel from exposure to chemotherapy drugs" was claimed	Different

	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 Docetaxel [10mg/ml] >480 Oxaliplatin [5mg/ml] >480 Leucovorin [10mg/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.		
Color	Yellow	Blue	Different
Gown Style	Close-back	Close-back	Same
Sterility	Non-sterile	Non-sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
AAMI Level	AAMI Level 4	AAMI Level 3	Different
Made with natural rubber latex	No	No	Same
Body fabric	Spunbonded Polypropylene coated with Polyethylene (PPSB Coated PE materials)	PP SMS non-woven + PE	Different
Flammability	CPSC 16 CFR 1610:2010 Class 1	CPSC 16 CFR 1610:2010 Class 1	Identical
Thickness of Textile Materials	ASTM D1777-96 Avg. 0.14mm Meet claimed specification	Not reported in 510k Summary	N/A
Basic Weight	ASTM D3776/D3776M-20 Between 40 ± 2 g/m2 Meet claimed specification	ASTM D3776/D3776M-20 Meet claimed specification	Identical

Liquid Barrier Performance	ANSI/AAMI PB70:2012 All areas tested meet Level 4 performance requirements	ANSI/AAMI PB70:2012 All areas tested meet Level 3 performance requirements	Different
Trapezoid Test Tear Strength	ASTM F3352 - 19 /ASTM D5733-99 Seam Strength in critical zone CD >=10N (>=2.3 lbf) MD >=10N (>=2.3 lbf)	ASTM F3352 - 19 /ASTM - D5587 Seam Strength in critical zone CD >=10N (>=2.3 lbf) MD >=10N (>=2.3 lbf)	Different
IGrab Tensile Strength	ASTM D5034-17 Breaking strength CD>=30N (7 lbf) MD>=30N (7 lbf)	ASTM D5034 Breaking strength CD>=30N (7 lbf) MD>=30N (7 lbf)	Identical
Seam Strength test	ASTM D1683/D1683M-17(R18) 12.0 (9.7/ 14.2 lbf) (>=7 lbf)	Not reported in 510k Summary	N/A
Hydrostatic Pressure	AATCC Test Method 127 Hydrostatic Pressure(cm):>50cmH2O	AATCC Test Method 127 Hydrostatic Pressure(cm):>50cmH2O	Identical
Impact Penetration	AATCC Test Method 42 Water Impact(g)：≤1.0	AATCC Test Method 42 Water Impact(g)：≤1.0	Identical
Resistance to Linting of Nonwoven Fabrics (Dry)	ISO 9073-10 Particulate size range(μm): 3 to 25 Coefficient of linting <=4.0	ISO 9073-10 Particulate size range(μm): 1 to 25 Coefficient of linting <=4.0	Identical
Resistance to Penetration by Blood-Borne Pathogens	ANSI/AAMI Standard PB70 Level 4 / ASTM F1671/F1671M-13 Penetration Does Not Appear	Not reported in 510k Summary	Different
Cytotoxicity, ISO10993-5	Non-cytotoxic	Non-cytotoxic	Identical
Irritation, ISO10993-10	Non-irritating	Non-irritating	Identical
Sensitization, ISO10993-10	Non-sensitizing	Non-sensitizing	Identical

To compare with the legal marketed Chemo gown, another cleared device, Cardinal Health ChemoPlus Full Coverage Gown, Closed Back, Non-sterile, was selected for reference. The following is a summary of the technological characteristics of **CoverU Disposable Gown with Tape - Chemo Gown, Model number: IL-4036YKTP-CM** as compared to the reference device.

Items	Subject Device The CoverU Disposable Gown with Tape Chemo Gown, Model number: IL-4036YKTP-CM (K210414)	Reference Device Cardinal Health ChemoPlus Full Coverage Gown, Closed Back, Non-sterile (K193327)	Comparison Result
Submitter	MEDTECS (TAIWAN) CORP.	Cardinal Health 200, LLC	N/A
Device Regulation number	21 CFR 878.4040	21 CFR 878.4040	Same
Classification	2	2	Same
FDA Product Code	FYC, QSO	FYA	Different

Indications for Use	The CoverU Disposable Gown with Tape - Chemo Gown (Model number IL-4036YKTP-CM) is intended to provide barrier protection and protect healthcare personnel and patients from the transfer of microorganisms, body fluids and particulate material. CoverU Disposable Gown with Tape meets the requirements of AAMI Level 4 barrier protection for a surgical isolation gown per ANSI/ AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. Not intended for use in the operating room. CoverU Disposable Gown with Tapes is a single use, disposable medical device provided non-sterile. 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	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. The non-sterile, closed back gowns are not intended for use in the operating room. 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] >	Similar

	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 Docetaxel [10mg/ml] >480 Oxaliplatin [5mg/ml] >480 Leucovorin [10mg/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.	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.	

Prescription for use	No	No	Same
AAMI Level	AAMI Level 4	AAMI Level 3	Different
Over the Counter	Yes	Yes	Same
Drug claimed for protection	15 drugs • Carmustine • Cisplatin • Cyclophosphamide • **Cytarabine Hydrochloride** • Dacarbazine • **Daunorubicin Hydrochloride** • Doxorubicin Hydrochloride • Etoposide • Fluorouracil • **Ifosfamide** • Methotrexate • Mitomycin C • Paclitaxel • Thiotepa • Vincristine Sulfate	12 drugs • Carmustine • Cisplatin • Cyclophosphamide • Dacarbazine • Doxorubicin Hydrochloride • Etoposide • Fluorouracil • Methotrexate • Mitomycin C • Paclitaxel • Thiotepa • Vincristine Sulfate	Different

Summary of Non-Clinical Performance Testing			
Resistance to permeation of chemotherapy drugs test	ASTM F739-12 Results showed no average standardized breakthrough for up to 480 minutes for claimed 15 drugs	ASTM F739-12 Results showed no average standardized breakthrough for up to 480 minutes for claimed 12 drugs	Similar

Discussion

The difference in the designs, materials and colors does not raise additional questions for safety and effectiveness. Performance testing including biocompatibility evaluation has been performed on the final finished device which includes all construction materials and color additives.

Summary of Non-Clinical Testing

Per Guidance for Industry and FDA Staff: Premarket Notification Requirements Concerning Gowns Intended for Use in Healthcare Settings, the following standards and the requirements have been confirmed for CoverU Disposable Gown with Tape:

- AATCC 42: Test Method for Water Resistance: Impact Penetration
- AATCC TM127-2017: Test Method for Water Resistance: Hydrostatic Pressure
- ASTM F1671/F1671M-13, Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System
- ASTM D3776/D3776M (2020), Test Methods for Mass Per Unit Area (Weight) of Woven Fabric.
- ASTM D5034-09(2013), Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test).
- ASTM D5733-99, Standard Test Method for Tear Strength of Non Woven Fabrics by Trapezoid Procedure
- ASTM D1683/D1683M-17, Standard Test Method for Failure in Sewn Seams of Woven Fabrics
- ASTM D1777-96(2019): Standard Test Method for Thickness of Textile Materials
- CPSC 16 Part 1610, Standard for The Flammability of Clothing Textiles.
- ASTM F739 - 12, Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact
- ISO 10993- 1: 2009/(R)2013, Biological Evaluation of Medical Devices- Part 1: Evaluation and testing within a risk management process.

- ISO 10993-5: 2009 Biological Evaluation of Medical Devices – Part 5: Tests ForIn Vitro Cytotoxicity.
- ISO 10993-10: 2010 Biological Evaluation of Medical Devices – Part 10: Tests For Irritation And Skin Sensitization.
- ISO 9073-10:2004, Textiles-Test methods for nonwovens-Part 10: Lint and other particles generation in the dry state.

Test Summary Table

Test Performed	Purpose	Test method/ Standard followed	Acceptance Criteria	Test result
Hydrostatic pressure	To determine the hydrostatic pressure of the test sample.	ATCC 127/AAMI Standard PB70 Level 4	>50 cm H2O	Pass
Water impact	The test was performed to determine the Water impact of the test sample.	ATCC 42/AAMI Standard PB70 Level 4	≤1.0 g	Pass
Resistance of Materials to Penetration by Viral	T0 measure blood-borne pathogens using a surrogate microbe under conditions of continuous liquid contact.	ASTM F1671/F1671M-13/ ANSI/AAMI Standard PB70 Level 4	Penetration Does Not Appear	Pass
Basic weight	To determine the Basic weight of the test article.	ASTM D3776 / D3776M (2020)	Avg. 40 g/m2 ±5%	Pass
Grab Tensile Strength	To evaluate the breaking strength of the test sample by test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	ASTM D5034-09(2017) /ASTM D5034-09(2017)	Tensile strength >=7 lbf (>=30N)	Pass
Seam Strength	To evaluate the seam	ASTM D1683 / D1683M - 17(2018)	Seam Strength in critical zone >=7 lbf(>=30N)	Pass

Test Performed	Purpose	Test method/ Standard followed	Acceptance Criteria	Test result
	strength of the test sample by the method of Failure in Sewn Seams of Woven Fabrics			
Trapezoid Test Tear Strength	To evaluate the tearing strength of the test sample.	ASTM D5733-99/ASTM D5733-99	Seam Strength in critical zone >=10N (>=2.3 lbf)	Pass
Flammability	The test was performed in accordance with 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles to evaluate the flammability of the test sample.	16 CFR Part 1610/ASTM F2407-06(2013) e1, Section 6.3 flame spread	Class 1 does not Ignite	Pass
Resistance to Linting of Nonwoven Fabrics (Dry)	To evaluate the linting of the test sample by the method of Nonwovens-Pat 10: Lint and Other Particles Generation in the Dry State	EN ISO 9073-10:2004/EN 13795-1:2019	Requirement Coefficient of linting <=4.0	Pass
Resistance to permeation of chemotherapy drugs test	To measure the absorbance of test chemicals, which permeated through the specimens into the collection medium.	ASTM F739-12	Results showed no average standardized breakthrough for up to 480 minutes for claimed 15 drugs	Pass

Test Performed	Purpose	Test method/ Standard followed	Acceptance Criteria	Test result
Cytotoxicity	To evaluate the cytotoxicity of the test ample.	ISO10993-5	the averaged result which concluded that the "Disposable Isolation Gown" extract did not induce cytotoxic to L929 cells.	Pass
Irritation	To evaluate the irritation of the test sample.	ISO10993-10	No erythema and no edema were observed on the skin of the rabbits. Furthermore, the PII values were 0.	Pass
Sensitization	To evaluate the sensitization of the test sample.	ISO10993-10	The submitted sample under the conditions of this study, the test article extract showed no evidence of causing delayed dermal contact sensitization in the guinea pig.	Pass

Summary of Clinical Testing:

Clinical testing is not needed for the subject devices.

Conclusions:

The conclusion drawn from the non-clinical tests demonstrates that the subject device, the CoverU Disposable Gown with Tape AAMI Level 4 Isolation Gown and CoverU Disposable Gown with Tape - Chemo Gown, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K190306.