October 4, 2023

Copioumed International Inc.
% Ming-Yie Jan
Principle Consultant
RusCert Technology Co., Ltd.
8F., No. 187, Lequn 2nd Rd., Zhongshan Dist.
Taipei City, 10462
Taiwan

Re: K230135
Trade/Device Name: Copioumed Chemotherapy Isolation Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYC, QSO
Dated: August 28, 2023
Received: September 5, 2023

Dear Ming-Yie Jan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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)*
K230135

Device Name
Copioumed Chemotherapy Isolation Gown

Indications for Use *(Describe)*

Copioumed Chemotherapy Isolation Gown 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. Copioumed Chemotherapy Isolation Gown is non-sterile and for single use only.

Copioumed Chemotherapy Isolation Gown 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).

Copioumed Chemotherapy Isolation Gown is a disposable device intended to protect health care personal from exposure to chemotherapy drugs during preparation, handling, and administration.

The Copioumed Chemotherapy Isolation Gown has been evaluated for resistance to permeation of various chemotherapy drugs per ASTM F739-20 "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
Etoposide [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

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.

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510(k) SUMMARY

A.	510(K) NUMBER	K230135
B.	DATE PREPARED	September 27, 2023
C.	SUBMITTER	COPIOUMED INTERNATIONAL INC.
D.	CONTACT PERSON	Primary Contact Title: General Manager Name: James Liu Tel: + 886 928 644 966 E-Mail: james.liu@gcv.com.tw Official Correspondent Title: Principal Consultant Name: Ming-Yie Jan Tel: + 8886 2 8785 8989 E-Mail: mingyie.jan@ruscert.net
E.	SUBJECT DEVICE	Proprietary Name: Copioumed Chemotherapy Isolation Gown Product Code: FYC, QSO Classification Names: Gown, Isolation, Surgical; Medical Gowns With Chemotherapy Labeling Claims - Tested For Use With Chemotherapy Drugs Regulation Number 21 CFR 878.4040 Regulation Name: Surgical Apparel Device Class: Class II Review Panel: General Hospital
F.	INDICATIONS FOR USE	Copioumed Chemotherapy Isolation Gown 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. Copioumed Chemotherapy Isolation Gown is non-sterile and for single use only. Copioumed Chemotherapy Isolation Gown 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). Copioumed Chemotherapy Isolation Gown is a disposable device intended to protect health care personal from exposure to chemotherapy drugs during preparation, handling, and administration. The Copioumed Chemotherapy Isolation Gown has been evaluated for resistance to permeation of various chemotherapy drugs per ASTM F739-20 "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
Etoposide [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

G. PREDICATE DEVICE	Proprietary Name: AMD Ritmed AssureWear VersaGown Product Code: FYC Regulation Number: 21 CFR 878.4040 Regulation Name: Surgical Apparel 510(k) Number: K190306 510(k) Submitter: AMD Medicom Inc. Device Class: Class II Review Panel: General Hospital
H. REFERENCE DEVICE	Proprietary Name: CoverU Disposable Gown with Tape - Chemo Gown Product Code: FYC, QSO Regulation Number: 21 CFR 878.4040 Regulation Name: Surgical Apparel 510(k) Number: K210414 510(k) Submitter: Medtecs (Taiwan) Corp. Device Class: Class II Review Panel: General Hospital
I. DEVICE DESCRIPTION	Copioumed Chemotherapy Isolation Gown is a disposable device intended to protect health care personal from exposure to chemotherapy drugs during preparation, handling, and administration. This device is non-sterile and for single use only. Copioumed Chemotherapy Isolation Gown is a Polypropylene Gown laminated with Polyethylene and Knit cuff in three styles: Tie neck closure, Velcro neck closure and Sticker neck closure.

J. COMPARISON OF CHARACTERISTICS WITH THE PREDICATE DEVICE

Elements of Comparison	**Proposed Device:** Copioumed Chemotherapy Isolation Gown K230135	**Predicate Device:** AMD Ritmed AssureWear VersaGown K190306	**Comparisons**
Product Code	FYC, QSO	FYC	Same for FYC
Intended Use/Indications for Use	Copioumed Chemotherapy Isolation Gown 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. Copioumed Chemotherapy Isolation Gown is non- sterile and for single use only. Copioumed Chemotherapy Isolation Gown 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). Copioumed Chemotherapy Isolation Gown is a disposable device intended to protect health care personal from exposure to chemotherapy drugs during preparation, handling, and administration. The Copioumed Chemotherapy Isolation Gown has been evaluated for resistance to permeation of various chemotherapy drugs per ASTM F739-20 "Standard Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact."	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™ VersaGown 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 X-large sizes. Flexneck Models Flexneck Plus Models Tie Models A69964 A69933 A8300 A69965 A69934 A8301 A69966 A69935 A8302 A69967 A69936 A8303 A69968 A69937 A8304 A69969 A69938 A8305	Same: 1. AAMI Level 3 Isolation Gowns 2. Meet the requirements of level 3 Liquid Barrier Performance as per AAMI PB70:2012 3. Non-sterile and single use only. Similar[1]: 1. Protection description Different[1]: 1. Evaluated for resistance to permeation of various chemotherapy

	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 Etoposide [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		
Material Composition	Polypropylene Gown laminated with polyethylene	PP SMS non-woven + PE	Similar[2]
Design Features	Knit cuff in three style(model) Tie neck closure, Velcro neck closure and Sticker neck closure	Thumb loop Elastic cuffs Extended cuff (Thumb loop) Flexneck™ Tie (neck) Straight sleeve Inclined sleeve Blue belt tie	Similar[3]
Sterility	Non-sterile	Non-sterile	Same
Color	Blue	Blue	Same
Use	OTC	OTC	Same
Contact Durations	Surface, < 24 hours	Surface, < 24 hours	Same
Disposable	Disposable	Disposable	Same

Single Use/Reusable	Single Use	Single Use	Same
Performance per AAMI PB70:2012	AAMI Level 3	AAMI Level 3	Same
Basis weight ASTM D3776	51.2 ± 1.2 g/m^2 (1.5 oz/yd^2 ± 0.04)	39.97 ± 1.61 g/m^2 (1.17 oz/yd^2 ± 0.05)	Similar[5]
Liquid barrier performance: Hydrostatic Pressure AATCC 127	Pass. Met the standard's requirement (≥ 50 cm H2 O) Testing targets: main body fabric, sleeve seam, shoulder seam, belt, armpit	Chest: 109.34 ± 0.34 cmH2O Sleeve seams: 110.67± 3.84 cmH_2O Belt attachments: 104 ± 5.19 cmH_2O Body/sleeve/belt mean: 108 ± 3.1 cm H_2O	Similar[6]
Liquid barrier performance: Impact Penetration AATCC 42	Pass, Met the standard's requirement. (≤ 1.0 g)	Chest: <0.1 g Sleeve seams: <0.1 g Belt attachments: < 0.1 g Body/sleeve/belt mean: <0.1 g	Same
Breaking strength (MD) ASTM D5034	15.8 ± 3.7 lbf	18.17 ± 0.31 lbf	Similar[7]
Breaking strength (CD) ASTM D5034	12.25 ± 1.95 lbf	11.78 ± 0.33 lbf	Similar[8]
Tearing strength (MD) ASTM D5587-08	6.3 ± 1.7 lbf	11.01 ± 0.64 lbf	Similar[9]
Tearing strength (CD) ASTM D5587	3.6 ± 0.8 lbf	5.30 ± 0.35 lbf	Similar[10]
Biocompatibility	Under the test conditions, the subject device was shown to be noncytotoxic, non-irritating and non-sensitizing per ISO 10993-5, ISO 10993-10, and ISO 10993-23.	Under the test conditions, the subject device was shown to be noncytotoxic, non-irritating and non-sensitizing per ISO 10993-5 & ISO 10993-10.	Same
Flammability 16 CFR Part 1610.7	Meets requirements of Flame Resistant CPSC 16 CFR 1610 Class 1	Meets requirements of Flame Resistant CPSC 16 CFR 1610 Class 1	Same

Similarity[1]: The proposed device and predicate device have the same isolation protection description. The proposed device also emphasizes on the protection of chemotherapy drugs. This difference does not affect the safety and efficacy of the proposed gown.
Similarity[2]: Even though the description of materials for proposed device and predicate device are slightly different, it shall be the same materials or similar materials. Therefore, this difference does not raise any concerns on safety and efficacy.

Similarity[3,] The predicate device has more various designs on gowns and the main different designs of proposed device are on the neck. The design of the gown has been evaluated in different tests which does not raise any concerns about safety and efficacy.
Similarity[5]: Theses gowns were tested using the ASTM D3776 standard testing methods. As there were no limit or criteria for this test, the test values of proposed device passed has passed the criteria set by Copioumed International INC. The bigger values of testing results do not raise extra concerns of safety and efficacy.
Similarity[6]: The testing targets of proposed device have covered the testing targets of predicate device. The proposed device also tested the armpit and shoulder seam. All the testing results of proposed device and predicate device met the criteria of standard.
Similarity[7, 8]: The proposed device and predicate device were tested for "breaking strength" using ASTM D5034. The breaking strength of the proposed device differed from the predicate device but were within the acceptance criteria. Therefore, the difference does not raise any questions on the safety and effectiveness of the proposed device.
Similarity[9,10]: The proposed device and predicate device were tested for "breaking strength" using ASTM D5587. The breaking strength of the proposed device differed from the predicate device but were within the acceptance criteria.
Different[1]: The predicate device does not test the resistance to permeation of various chemotherapy drugs.

K. COMPARISON TO REFERENCE DEVICE
In order to compare with the legal marketed Chemo gown, another cleared device, K210414, CoverU Disposable Gown with Tape - Chemo Gown, was selected for reference to demonstrate the evaluated for resistance to permeation of various chemotherapy drugs.

Elements of Comparison	**Proposed Device:** Copioumed Chemotherapy Isolation Gown K230135	**Reference Device:** CoverU Disposable Gown with Tape - Chemo Gown K210414	**Comparisons**
Product Code	FYC, QSO	FYC, QSO	Same
Intended Use/Indications for Use	Copioumed Chemotherapy Isolation Gown 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. Copioumed Chemotherapy Isolation Gown is non- sterile and for single use only. Copioumed Chemotherapy Isolation Gown 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).	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	Similar[11]: 1. Reference device is only chosen to demonstrate the evaluated for resistance to permeation of various chemotherapy drugs

	Copioumed Chemotherapy Isolation Gown is a disposable device intended to protect health care personal from exposure to chemotherapy drugs during preparation, handling, and administration. The Copioumed Chemotherapy Isolation Gown has been evaluated for resistance to permeation of various chemotherapy drugs per ASTM F739-20 "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 Etoposide [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	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 [l0mg/ml] >480 Oxaliplatin [5mg/ml] >480 Leucovorin [1 0mg/ml] >480 *No permeation was detected at either the minimum detectable permeation or 0.1 g/cm2/min	

	Vincristine Sulfate [1 mg/ml] >480 *No permeation was detected at either the minimum detectable permeation or 0.1 µg/cm2/min		
Material Composition	Polypropylene Gown laminated with polyethylene	Spunbonded Polypropylene coated with Polyethylene (PPSB Coated PE materials)	Different[2]
Design Features	Knit cuff in three style(model) Tie neck closure, Velcro neck closure and Sticker neck closure	Close-back	Similar[12]
Sterility	Non-sterile	Non-sterile	Same
Color	Blue	Yellow	Different[3]
Use	OTC	OTC	Same
Disposable	Disposable	Disposable	Same
Single Use/Reusable	Single Use	Single Use	Same
Performance per AAMI PB70:2012	AAMI Level 3	AAMI Level 4	Different[4]

Resistance to permeation of chemotherapy drugs testing	ASTM F739-20 Results showed no average Standardized breakthrough for up to 480 minutes for claimed 16 drugs. 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 Etoposide [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	ASTM F739-12 Results showed no average standardized breakthrough for up to 480 minutes for claimed 19 drugs 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 Docetaxel [l0mg/ml] >480 Oxaliplatin [5mg/ml] >480 Leucovorin [1 0mg/ml] >480 *No permeation was detected at either the minimum detectable permeation or 0.1 g/cm2/min	Similar[13]

Similar[11]The reference device is only chosen to demonstrate the evaluated for resistance to permeation of various chemotherapy drugs. Both proposed device and reference device were tested for resistance to permeation of various chemotherapy drugs per the Consensus Standard ASTM F739-20, Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact. The reference device was tested for three more drugs than the subject device. The tested drugs are listed clearly in labeling with the proposed device.
Similar[12]: The reference device has similar designs, offering protective backs.
Different[2,3]: The proposed device and reference device utilize different textiles and are different colors. Both meet their respective performance test requirements.

Different[4]: Even the proposed device and reference device are different level of protection, the main reason to choose the reference device is to demonstrate the evaluated for resistance to permeation of various chemotherapy drugs.

The reference device, a chemo gown meeting AAMI PB70 Level 4 barrier performance, relies upon ASTM F739-12 to demonstrate its resistance to listed chemotherapy drug permeation. ASTM F739-20, the version of the standard currently recognized, is used to demonstrate the barrier performance for tested chemotherapy drugs in the subject AAMI PB70 Level 3 chemotherapy isolation gown.

L. SUMMARY OF NON-CLINICAL TESTING

No.	Standards	Purpose	Criteria	Results
1.	AATCC 42	To demonstrate resistance to penetration of sprayed water	≤1.0 g	Pass
2.	AATCC 127	To demonstrate resistance to penetration of pressurized water	≥50 cm H_2O	Pass
3.	ANSI/AAMI PB70:2012 AAMI Level 3	To demonstrate adequate liquid barrier performance	Level 3	Pass
4.	ASTM F739-20	To demonstrate resistance to penetration of chemotherapy drugs	≥480 minutes	Pass
5.	ASTM D3776/D3776M-17	To determine the mass of the fabric	Informative	Pass
6.	ASTM D5034 – 9 2017	To demonstrate adequate tensile strength of the material	≥30 N	Pass
7.	ASTM 1683-17 (2018)	To demonstrate adequate seam strength	≥30 N	Pass
8.	ASTM D5587-15 (2019)	To demonstrate adequate tear strength of the material	≥10 N	Pass
9.	NWSP 160.1	To determine the linting properties	Informative	Pass
10.	ISO 9073-10:2003	To determine linting properties	Informative	Pass
11.	16 CFR 1610	Standard for the Flammability for Clothing Textiles	Class 1	Pass
12.	ISO 10993-5:2009	To assess the potential cytotoxicity of the gown	Under the conditions of the testing, non-cytotoxic	Pass
13	ISO 10993-10:2021	To assess the sensitization potential of the gown	Under the conditions of the testing, not a sensitizer	Pass
14	ISO 10993-23:2021	To assess the irritation potential of the gown	Under the conditions of the testing, not an irritant	Pass

M. SUMMARY OF CLINICAL TESTING

No clinical testing was performed in support of this 510(k)

N. CONCLUSION	The conclusions drawn from the non-clinical testing demonstrate that the subject device, Copioumed Chemotherapy Isolation Gown, is as safe, as effective, and performs as well as or better than the legally marketed predicate device K190306.