January 17, 2020

AMD Medicom Inc.
Nektaria Markoglou
Director, Product Innovation and Development
2555 Chemin de l'Aviation
Pointe-Claire, Montreal, H9P2Z2 Ca

Re: K190306
Trade/Device Name: AMD Ritmed AssureWear VersaGown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYC
Dated: December 16, 2019
Received: December 17, 2019

Dear Nektaria Markoglou:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Elizabeth Claverie, M.S.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190306

Device Name
AMD Ritmed AssureWear™ VersaGown

Indications for Use *(Describe)*
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

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.

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510(k) Summary

510(k) Number:	K190306
Manufacturer:	AMD Medicom, Inc. 2555 Chemin de l'Aviation, Pointe-Claire, Quebec, H9P 2Z2, Canada
Phone Number:	514-636-6262
Contact Person:	Nektaria Markoglou
Date Prepared:	January 14, 2020
Trade Name:	AMD Ritmed AssureWear™ VersaGown
Regulation Number:	21CFR878.4040
Regulation Name:	Surgical Apparel
Device Class:	Class II
Product Code:	FYC
Device Classification Name	Gown, Isolation, Surgical
Predicate Device	Cardinal Health™ Isolation Gowns (K160339)

Device Description

AMD Ritmed AssureWear™ VersaGown 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 material. AMD Ritmed 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, disposable medical device provided non-sterile and non-intended for use in operating rooms and is constructed of polypropylene Spunbond--Meltblown-Spunbond Nonwovens (SMS), non-woven and coated with polyethylene. The isolation gown consists of one critical zone throughout the entire gown including the seams and belt attachments but excluding cuffs, hems and bindings.

AMD Ritmed AssureWear™ VersaGown is available with the following variations:

Wrist
- Elastic cuffs- Thumb loop
- Elastic cuffs- Extended cuff (Thumb loop)
- Elastic cuffs

Sleeves
- Straight
- Inclined

Color
- Blue

Neck Closure
- Flexneck™
- Flexneck™ Plus
- Tie

Sizes
- Large
- X-large

The Flexneck™ is comprised of unique and flexible, latex-free, double elastic closure that creates the widest head opening.

Indication for Use

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
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A69968	A69937	A8304
A69969	A69938	A8305

Predicate Device

Cardinal Health™ Isolation Gown, K160339

Technological Characteristics Comparison Table

The table below compares the construction, technology, design, claims and intended use of AMD Ritmed AssureWear™ VersaGown and the predicate device.

Comparison Component			**AMD Ritmed AssureWear™ VersaGown** (subject device)	**Cardinal Health™ Isolation Gown** (predicate device)	**Comparison**
Manufacturer			AMD Medicom Inc.	Cardinal Health LLC	
510 K number			K190306	K160339	
Intended use			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. AMD Ritmed AssureWear™ VersaGown is a single use, disposable medical device provided non-sterile and non-intended for use in operating rooms.	Cardinal Health isolation Gown is intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operation room. The Cardinal Health Isolation Gown is a single use, disposable medical device provided non-sterile.	Same
Level of barrier protection AAMI PB70			Level 3	Level 3	Same
Technology			N/A	N/A	Same
Material composition			PP SMS non-woven + PE	PE SMS non-woven	Similar
Design			Thumb loop Elastic cuffs Extended cuff (Thumb loop) Flexneck™ Tie (neck) Straight sleeve Inclined sleeve Blue belt tie Reinforced seams	Medical tape Neck closure White belt tie Elastic cuffs	Similar for all designs except for the Flexneck patented design
Color			Blue	Blue and yellow	Similar
Sterility			Non- Sterile	Non- Sterile	Same
Use			Single use; disposable	Single use; disposable	Same
Non-clinical Performance					
Basic weight ASTM D3776			39.97 ± 1.61 g/m^2 (1.17 oz/yd^2 ± 0.05)	41 g/m^2 (1.21 oz/yd^2)	Similar
Liquid barrier performance	**Hydrostatic Pressure AATCC 127**		Chest: 109.34 ± 0.34 cmH_2O 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	Body/sleeve mean: 69	Similar
	Impact penetration AATCC 42		Chest: <0.1 g Sleeve seams: <0.1 g Belt attachments: < 0.1 g Body/sleeve/belt mean: <0.1 g	Body/ sleeve mean: 0.08	Similar

Comparison Component		AMD Ritmed AssureWear™ VersaGown (subject device)	Cardinal Health™ Isolation Gown (predicate device)	Comparison of Technological Characteristics
Flammability	**16 CFR Part 1610.7**	Class I	Class I	Same
Breaking strength (MD) ASTM D5034		18.17 ± 0.31 lbf	22.23 lb	Similar
Breaking strength (CD) ASTM D5034		11.78 ± 0.33 lbf	14.18 lb	Similar
Tearing strength (MD) ASTM D5587		11.01 ± 0.64 lbf	4.40 lb	Similar
Tearing strength (CD) ASTM D5587		5.30 ± 0.35 lbf	7.99 lb	Similar
Linting (ISO 9073-10)		Particulate size range(μm): 1 to 25 Outside: Total linting >0.3 : 2.07; >0.5 : 1.97 Index for Particulate Matter (IPM): 1.50 Inside: Total linting >0.3 : 2.16; >0.5 : 2.00 Index for Particulate Matter (IPM): 1.35	N/A	NA
Biocompatibility	**Irritation ISO 10993-10**	Under the condition of the study, not an irritant	Under the condition of each study is non-cytotoxic, non-irritating, and non-sensitizing	Same
	Sensitization ISO 10993-10	Under the condition of the study, not a sensitizer		Same
	Cytotoxicity ISO 10993-5	Under the condition of the study, non- cytotoxic		Same

Non-Clinical Performance

The following standards were utilized in performance and biocompatibility testing of the AMD Ritmed AssureWear™ VersaGown.

	Standards Organization	Standards Title
PB70	AAMI	AAMI PB70 Liquid Barrier Performance Classification of Protective Apparel
TM 127	AATCC	Water Resistance: Hydrostatic Pressure Test
TM 42	AATCC	Water Resistance: Impact Penetration Test
D3776	ASTM	Test Methods for Mass Per Unit Area Weight of Woven Fabric
D5034	ASTM	Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)
D5587	ASTM	Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure
Part 1610	CPSC	Standard for the Flammability of Clothing Textiles

9073-10	ISO	ISO 9073-10 Textiles-Test methods for nonwovens-Part 10: Lint and other particles generation in the dry state.
10993-1	ISO	ISO 10993-1 Biological Evaluation of Medical Devices- Part 1: Evaluation and
10993-5	ISO	Biological Evaluation of Medical Devices- Part 5: Tests for In-Vitro Cytotoxicity
10993-10	ISO	Biological Evaluation of Medical Devices- Part 10: Tests for irritation and delayed-type hypersensitivity

Clinical Performance

Not applicable

Conclusion

The conclusions drawn from the nonclinical test demonstrate that the AMD Ritmed AssureWear™ VersaGown is as safe, as effective, and performs as well as or better than the legally marketed device, Cardinal Health™ Isolation Gowns (K160339).