January 20, 2022

Wuhan Zonsen Medical Products Co., Ltd
Cynthia Ye
General Manager
No 8 Jinchao Road, Zhucheng Street, Xinzhou District
Wuhan, Hubei 431000
China

Re: K212357
Trade/Device Name: Surgical isolation gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYC
Dated: November 16, 2021
Received: December 21, 2021

Dear Cynthia Ye:

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
Clarence W. Murray III, 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)*
K212357

Device Name
Surgical Isolation Gown

Indications for Use *(Describe)*
The Surgical 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 operating room. In addition, the Surgical Isolation Gown meets the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities. The Surgical Isolation Gown 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.

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510(K) Summary

510(k) Number: K212357
Revised date: January 17, 2022

A. Applicant:

Wuhan Zonsen Medical Products Co., Ltd
Address: No 8 Jinchao Road, Zhucheng Street, Xinzhou District, Wuhan City, Hubei
Contact Person: Cynthia Ye
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Fax: +86- 27-82737772

Submission Correspondent:
Primary contact: Cynthia Ye
Tel: +86-27-82737771
Email: info@zonsenmed.com
Secondary contact: Cynthia Ye
Tel: +86-27-82737772
Email:Cynthia@zonsenmed.com

B. Device:

Trade Name: SURGICAL ISOLATION GOWN
Common Name: ISOLATION GOWN
Model(s): ZIG 1256

Regulatory Information
Classification Name: Surgical Isolation Gown
Classification: Class II
Product code: FYC
Regulation Number: 878.4040
Review Panel: Surgical Apparel

C. Predicate device:

K190306
AMD Ritmed AssureWear™ VersaGown
AMD Medicom, Inc.

D. Reference device:

K171535
Surgical Isolation Gown
Jingzhou Haixin Green Cross Medical Products Co., Ltd

E. Indications for use :

The Surgical 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 operating room. In addition, the Surgical Isolation Gown meets the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities. The Surgical Isolation Gown is a single use, disposable medical device provided non-sterile.

F. Device Description:

The Proposed device is a surgical isolation gown with moderate barrier protection identified by Regulation 21 CFR 878.4040 under FDA product code, FYC and is a single use, disposable medical device provided non-sterile. The Surgical Isolation Gown is constructed of the body, the neck tie, the waist belt, and elastic cuffs. The body fabric material is Polypropylene SMS non-woven, coated with Polyethylene. And all seams are reinforced by sealing tape of 100% Polyurethanes. The Surgical Isolation Gown is offered in blue with seven sizes (S, M, L, XL, XXL, 3XL, 4XL).

The Surgical Isolation Gown has been tested according to ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities and meets AAMI Level 3 requirement.

G. Comparison with predicate device

Table1

Comparison Component	**Proposed Device**	**Predicate Device**	**Reference Device**	**Comparison**
Manufacturer	Wuhan Zonsen Medical Products Co., Ltd	AMD Medicom, Inc.	Jingzhou Haixin Green Cross Medical Products Co., Ltd	/
510K number	K212357	K190306	K171535	/
Device name	Surgical isolation gown	AMD Ritmed AssureWear™ VersaGown	SURGICAL ISOLATION GOWN	/
Classification	Class II Device, FYC (21 CFR878.4040)	Class II Device, FYC (21 CFR878.4040)	Class II Device, FYC (21CFR878.4040)	Same
Intend use / Indications for use	The Surgical 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 operating room. In addition, the Surgical Isolation Gown meets the requirements of an AAMI	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	The Surgical 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 operating room. In addition, the Surgical Isolation Gown	Same

	Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities. The Surgical Isolation Gown is a single use, disposable medical device provided non-sterile.	medical device provided non-sterile and non-intended for use in operating rooms.	meets the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70). The Surgical Isolation Gown is a single use, disposable medical device provided non-sterile.	
Level of barrier protection AAMI PB70	Level 3	Level 3	Level 3	Same
Material composition	Polypropylene SMS non-woven + PE	PP SMS non-woven + PE	Polypropylene SMS non woven	Same as K190306
Design	Elastic cuffs Tie (neck) Blue waist belt Reinforced seams	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 Snap fastener	Similar to K190306
Color	Blue	Blue	Yellow	Same as K190306
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Same
Use	Single use; disposable	Single use; disposable	Single use; disposable	Same

Table 2

Non-clinical Performance				
Comparison Component	**Proposed Device (K212357)**	**Predicate Device (K190306)**	**Reference Device (K171535)**	**Comparison**
Basic weight ASTM D3776	40±2 g/m^2	39.97±1.61 g/m^2	Testing not	Similar

Non-clinical Performance					
Comparison Component		**Proposed Device (K212357)**	**Predicate Device (K190306)**	**Reference Device (K171535)**	**Comparison**
			(1.17 oz/yd^2 ± 0.05)	performed	to K190306
Liquid barrier performance	**AATCC 127 Hydrostatic Pressure** (cmH_2O)	Average: Front: 160.29* Back: 152.09* Sleeve: 152.03* Sleeve seam: 138.06* Shoulder seam: 146.50* Waistband seam: 72.19*	Chest: 109.34 ± 0.34 Sleeve seams: 110.67± 3.84 Belt attachments: 104 ± 5.19 Body/sleeve/belt mean: 108 ± 3.1	CHEST/BACK/SLEEVE: Mean = 69 Ind Min = 54 Ind Max = 84	Similar to K190306
	AATCC 42 Impact Penetration (g)	Front: <0.2 Back: <0.1 Sleeve: 0 Sleeve seam: 0 Shoulder seam: <0.1 Waistband seam: <0.1	Chest: <0.1 Sleeve seams: <0.1 Belt attachments: < 0.1 Body/sleeve/belt mean: <0.1	Sleeve Seams: Mean = 0.04 Ind Min = 0.02 Ind Max = 0.08 CHEST: Mean = 0.04 Ind Min = 0.02 Ind Max = 0.05 Back: Mean = 0.05 Ind Min = 0.04 Ind Max = 0.07	Similar
Flammability 16 CFR Part 1610-2008		Class I	Class I	Class I	Same
Tensile strength (MD) ASTM D5034		134N*	18.17 ± 0.31 lbf	Mean = 20.71 lbf Ind Min = 19.73 Ind Max = 21.87	Similar
Tensile strength (CD) ASTM D5034		80N*	11.78 ± 0.33 lbf	Mean = 12.21 lbf Ind Min = 11.20 Ind Max = 14.11	Similar
Tearing strength (MD) ASTM D5733		39N*	11.01 ± 0.64 lbf	Mean = 3.48 lbf Ind Min = 2.82 Ind Max = 3.93	Similar
Tearing strength (CD) ASTM D5733		21N*	5.30 ± 0.35 lbf	Mean = 7.15 lbf Ind Min = 6.20 Ind Max = 7.70	Similar
Seam strength ASTM 1683/D	**Sleeve seam**	65N*	Testing not performed	Testing not performed	/
	Armhole seam	65N*			

Non-clinical Performance					
Comparison Component		**Proposed Device (K212357)**	**Predicate Device (K190306)**	**Reference Device (K171535)**	**Comparison**
1683M-17 (2018)	**Shoulder seam**	62N*			
Linting (ISO 9073-10)		Particulate size range(μm): 3 to 25 Side A: Total linting: 61*; Coefficient of linting: 1.8* Side B: Total linting: 154*; Coefficient of linting: 2.1*	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	SIDE A: OUTSIDE TOTAL >0.3 1024 TOTAL >0.5 658 SIDE B: INSIDE TOTAL >0.3 1066 TOTAL >0.5 697	Better than K171535
ASTM F1868-17 Evaporative Resistance		>1.00 kPa.m^2/W	Testing not performed	Testing not performed	/
Biocompatibility	**Irritation ISO 10993-10**	Under the condition of the study, non irritating	Under the condition of the study, not an irritant	The test was done against ISO10993-5 and ISO10993-10. The result indicates the gown is noncytotoxic, non-irritating, and non-sensitizing per ISO 10993-1.	Same
	Sensitization ISO 10993-10	Under the condition of the study, non sensitizing	Under the condition of the study, not a sensitizer		Same
	Cytotoxicity ISO 10993-5	Under the condition of the study, non-cytotoxic	Under the condition of the study, non-cytotoxic		Same

Note: * means the average results of 3 non-consecutive lots,32 samples/ lot.

H. Summary of Non-Clinical Test

The Surgical Isolation gowns were tested following below standards:

- ISO10993-5 Biological evaluations of medical devices -- Part 5: Tests for In Vitro cytotoxicity;
- ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization;
- ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities;
- AATCC 42 Water Penetration Resistance: Impact Penetration Test;
- AATCC 127 Water Resistance: Hydrostatic Pressure Test;
- ASTM D5034-09 (Reapproved 2017) Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test) ;

- ASTM D5733-99 Test Method for Tearing Strength of Nonwoven Fabrics by the Trapezoid Procedure;
- ASTM D1683/ D 1683M-17(2018) Test methods for Failure in Sewn Seams of Woven Apparel Fabrics;
- 16 CFR 1610-2008 Standard for the Flammability of clothing textiles;
- ISO9073-10:2003 Textiles—Test methods for nonwovens—Part 10: Lint and other particles generation in the dry state;
- ASTM F1868-17 Test methods for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate.

Table 3 - Performance Testing

<table>
<tr><th colspan="2">Test Item</th><th>Requirement</th><th>Test results (Average, 32 samples/ lot)</th></tr>
<tr><td colspan="2">Flammability 16 CFR Part 1610-2008</td><td>Class I</td><td>Lot1: Class I
Lot2: Class I
Lot2: Class I</td></tr>
<tr><td colspan="2">AATCC 127 Hydrostatic Pressure (cmH_2O)</td><td>Level 3: >50</td><td><table><tr><td></td><td>Lot1</td><td>Lot2</td><td>Lot3</td></tr><tr><td>Front</td><td>151.6</td><td>165.4</td><td>163.7</td></tr><tr><td>Back</td><td>142.8</td><td>158.4</td><td>154.4</td></tr><tr><td>Sleeve</td><td>148.5</td><td>153.4</td><td>153.9</td></tr><tr><td>Sleeve seam</td><td>149.8</td><td>133.5</td><td>130.7</td></tr><tr><td>Shoulder seam</td><td>155.3</td><td>141.2</td><td>143.2</td></tr><tr><td>Waistband seam</td><td>99.5</td><td>59.1</td><td>58.3</td></tr></table></td></tr>
<tr><td colspan="2">AATCC 42 Impact Penetration (g)</td><td>Level 3:<1.0</td><td>Front: <0.2
Back: <0.1
Sleeve: 0
Sleeve seam: 0
Shoulder seam: <0.1
Waistband seam: <0.1</td></tr>
<tr><td rowspan="2">Tensile Strength ASTM D5034</td><td>MD</td><td>≥30N</td><td>Lot1: 135N
Lot2: 134N
Lot3: 133N</td></tr>
<tr><td>CD</td><td>≥30N</td><td>Lot1: 82N
Lot2: 80N
Lot3: 78N</td></tr>
<tr><td>Tearing Strength ASTM D5733</td><td>MD</td><td>≥10N</td><td>Lot1: 39N
Lot2: 39N
Lot3: 40N</td></tr>
</table>

<table>
<tr><td></td><td>CD</td><td>≥10N</td><td>Lot1: 22N
Lot2: 20N
Lot3: 20N</td></tr>
<tr><td rowspan="3">Seam Strength ASTM D1683/D 1683M-17(2018)</td><td>Sleeve seam</td><td rowspan="3">≥30N</td><td>Lot1: 60N
Lot2: 63N
Lot3: 73N</td></tr>
<tr><td>Armhole seam</td><td>Lot1: 64N
Lot2: 69N
Lot3: 62N</td></tr>
<tr><td>Shoulder seam</td><td>Lot1: 63N
Lot2: 63N
Lot3: 61N</td></tr>
<tr><td rowspan="2">Linting (ISO 9073-10)
Size of particles counted:3μm ~ 25μm</td><td>Total linting</td><td rowspan="2">/</td><td><table><tr><td></td><td>Side A</td><td>Side B</td></tr><tr><td>Lot1</td><td>61</td><td>200</td></tr><tr><td>Lot2</td><td>55</td><td>146</td></tr><tr><td>Lot3</td><td>66</td><td>115</td></tr></table></td></tr>
<tr><td>Coefficient of linting</td><td><table><tr><td></td><td>Side A</td><td>Side B</td></tr><tr><td>Lot1</td><td>1.8</td><td>2.2</td></tr><tr><td>Lot2</td><td>1.7</td><td>2.1</td></tr><tr><td>Lot3</td><td>1.8</td><td>2.0</td></tr></table></td></tr>
<tr><td colspan="2">ASTM F1868-17 Evaporative Resistance</td><td>/</td><td>Lot1: >1.0 kPa·m2 /W
Lot2: >1.0 kPa·m2 /W
Lot3: >1.0 kPa·m2 /W</td></tr>
</table>

Table 4 -Biological Specifications:

Performance	Requirement	Results
Cytotoxicity EN ISO10993-5	Non-Cytotoxic	PASS Per the Biocompatibility Evaluation, the proposed device is non-Cytotoxic.
Irritation EN ISO 10993-10	Non-Irritating	PASS Per the Biocompatibility Evaluation, the proposed device is non-Irritating.
Sensitization EN ISO 10993-10	Non-Sensitizing	PASS Per the Biocompatibility Evaluation, the proposed device is non-Sensitizing.

All the test results meet the requirement of ASTM F2407-20 Standard Specification For Surgical Gowns Intended for Use in Healthcare Facilities, and meet the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier Performance and

Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities.

I. Clinical Performance

Not applicable.

J. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed device identified.