February 26, 2026

Copioumed International, Inc.
% Ming-Yie Jan
Principal Consultant
Ruscert Technology Co., Ltd.
8f., # 187, Lequn 2nd Rd., Zhongshan Dist.
Taipei City, 10462
Taiwan

Re: K251860
Trade/Device Name: Copioumed AAMI 3 Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: January 26, 2026
Received: January 26, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

ALLAN GUAN -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection
Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251860

Device Name
Copioumed AAMI 3 Surgical Gown

Indications for Use *(Describe)*
Copioumed AAMI 3 Surgical Gown is intended to be worn by operating room personnel during surgical procedures to protect both surgical patient and the operating room personnel from the transfer of microorganisms, body fluids, and particulate materials. The gown is single-use, disposable, and provided sterile, and is classified as AAMI Level 3.

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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新 萬 盟 有 限 公 司
COPIOUMED INTERNATIONAL INC.

台北市復興北路 1號 16 樓之 4
16F-4, NO.1, FUXING N.RD., SONGSHAN DIST., TAIPEI CITY 105, TAIWAN (R.O.C.)
TEL:886-2-2772-1815 FAX:886-2-2711-9232

510(k) SUMMARY

This 510 (K) summary is being submitted in accordance with requirements of Title 21,CFR Section 807.92.

A.	510(k) NUMBER	K251860
B.	DATE PREPARED	February 17th, 2026
C.	SUBMITTER	COPIOUMED INTERNATIONAL INC. 16F-4, No.1, Fuxing N. Rd., Songshan Dist., Taipei City 105, Taiwan (R.O.C.) FEI Number: 9681151 Tel: +886 22772 1815
D.	CONTACT PERSON	Primary Contact Title: Chairman of the Board 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: +886 2 8785 8989 E-mail: FDA.sub@ruscert.net
E.	DEVICE	Proprietary Name: Copioumed AAMI 3 Surgical Gown Product Code: FYA Regulation Number: 21 CFR 878.4040 Regulation Name: Surgical Apparel Device Class: Class II Review Panel: General Hospital
F.	INDICATION(S) FOR USE	Copioumed AAMI 3 Surgical Gown is intended to be worn by operating room personnel during surgical procedures to protect both surgical patient and the operating room personnel from the transfer of microorganisms, body fluids, and particulate materials. The gown is single-use, disposable, and provided sterile, and is classified as AAMI Level 3.

G.	PRIMARY PREDICATE DEVICE	Proprietary Name: Cardinal Health™ Non-Reinforced Surgical Gown Product Code: FYA Regulation Number: 21 CFR 878.4040 Regulation Name: Surgical Apparel 510(k) Number: K170762 510(k) Submitter: Cardinal Health 200, LLC Device Class: Class II Review Panel: General Hospital
H.	DEVICE DECRIPTION	Copioumed AAMI 3 Surgical Gown provides protection with the materials of SMS. Copioumed AAMI 3 Surgical Gown has comfort and breathability and for a better fit on the user. The neck design of Copioumed Surgical Gown is adjustable and closes with a Velcro. Copioumed Surgical Gown is available in several sizes and lengths with two models (standard performance and high standard).
I.	COMPARISON OF CHARACTERISTICS WITH THE PREDICATE DEVICES	

B. Substantial Equivalence Comparison Table-Basic Information

Element of Comparison	**Proposed Device:** Copioumed AAMI 3 Surgical Gown K251860	**Predicate Device:** Cardinal Health™ Non-Reinforced Surgical Gown K170762	**Comparisons**
Product Code	FYA	FYA	N/A
Intended Use/Indications for Use	Copioumed AAMI 3 Surgical Gown is intended to be worn by operating room personnel during surgical procedures to protect both surgical patient and the operating room personnel from the transfer of microorganisms, body fluids, and particulate materials. The gown is single-use, disposable, and provided sterile, and is classified as AAMI Level 3.	The Cardinal Health™ Non-Reinforced Surgical Gowns are intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate material. In addition, this surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. The Cardinal Health™ Non-Reinforced Surgical Gowns are single use, disposable medical devices, provided sterile and non-sterile.	Similar
Materials	Polypropylene Gown laminated with polyethylene	Polyolefin (Polypropylene) SMS nonwoven	Same
Use	Single Use; Disposable	Single Use; Disposable	Same

Element of Comparison	**Proposed Device:** Copioumed AAMI 3 Surgical Gown	**Predicate Device:** Cardinal Health™ Non-Reinforced Surgical Gown K170762	**Comparisons**
Design Features	Knit cuff and Velcro in Standard Knit cuff and Velcro in High Performance	Neck Closure: Hook and Loop Belt Ties Knit Cuffs Transfer Tab	Similar
Sterility	Sterile	Sterile and non-sterile	For sterile products: Same
Sterilization Modality	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Same
Contact Durations	Surface, Intact, < 24 hours	Surface, Intact, < 24 hours	Same
Color	light blue	Dark blue	Different
Size	Standard: Size M, L, XL, XXL High Performance: M, L, XL, XXL	L, XL,2XL,3XL	Different

C. Substantial Equivalence Comparison Table-Predicate Device-Properties

<table>
<tr><th>Element of Comparison</th><th>Proposed Device:
Copioumed AAMI 3 Surgical Gown</th><th>Predicate Device[1]:
Cardinal Health™ Non-Reinforced Surgical Gown
K170762</th><th>Comparisons</th></tr>
<tr><td>Basis weight (oz/yd2)
ASTM D3776</td><td>40G±4G</td><td>
<table>
<tr><td colspan="2">Test Results (3 Lots)</td><td rowspan="2">Specification</td></tr>
<tr><td colspan="2">Mean (min/max)</td></tr>
<tr><td>Sleeve</td><td>Body</td><td></td></tr>
</table>
Unit[4]= oz/yd[2]
<table>
<tr><td>Mean = 1.32</td><td>Mean = 1.32</td><td>Target Mean= 1.30</td></tr>
<tr><td>Ind Min = 1.28</td><td>Ind Min = 1.28</td><td>Mean Min = 1.20</td></tr>
<tr><td>Ind Max = 1.36</td><td>Ind Max = 1.36</td><td>Ind Min = 1.07</td></tr>
</table>
</td><td>Similar[2]</td></tr>
<tr><td>Grab tensile, MD* (lbs)
ASTM D5034</td><td>MD≥55N</td><td>
<table>
<tr><td colspan="2">Test Results (3 Lots)</td><td rowspan="2">Specification</td></tr>
<tr><td colspan="2">Mean (min/max)</td></tr>
<tr><td>Sleeve</td><td>Body</td><td></td></tr>
</table>
Unit = lbs
<table>
<tr><td>Mean = 21.57</td><td>Mean = 21.57</td><td>N/A</td></tr>
<tr><td>Ind Min = 18.60</td><td>Ind Min = 18.60</td><td></td></tr>
<tr><td>Ind Max = 23.60</td><td>Ind Max = 23.60</td><td></td></tr>
</table>
</td><td>Similar[2]</td></tr>
</table>

<table>
<tr><th>Element of Comparison</th><th>Proposed Device:
Copioumed AAMI 3 Surgical Gown</th><th>Predicate Device[1]:
Cardinal Health™ Non-Reinforced Surgical Gown
K170762</th><th>Comparisons</th></tr>
<tr><td>Grab tensile, CD* (lbs)
ASTM D5034</td><td>CD≥40N</td><td>
<table>
<tr><td colspan="2">Test Results (3 Lots)</td><td rowspan="3">Specification</td></tr>
<tr><td colspan="2">Mean (min/max)</td></tr>
<tr><td>Sleeve</td><td>Body</td></tr>
</table>
Unit = lbs
<table>
<tr><td>Mean = 13.60</td><td>Mean = 13.60</td><td>Target Mean = 15.00</td></tr>
<tr><td>Ind Min = 11.20</td><td>Ind Min = 11.20</td><td>Mean Min = 11.00</td></tr>
<tr><td>Ind Max = 16.0</td><td>Ind Max = 16.0</td><td>Ind Min = 9.50</td></tr>
</table>
</td><td>Similar[2]</td></tr>
<tr><td>Trap Tear, MD* (lbs)
ASTM D5587-15 Highest Peak</td><td>MD≥10N</td><td>
<table>
<tr><td colspan="2">Test Results (3 Lots)</td><td rowspan="3">Specification</td></tr>
<tr><td colspan="2">Mean (min/max)</td></tr>
<tr><td>Sleeve</td><td>Body</td></tr>
</table>
Unit = lbs
<table>
<tr><td>Mean = 3.47</td><td>Mean = 3.47</td><td>Target Mean = 4.00</td></tr>
<tr><td>Ind Min = 2.73</td><td>Ind Min = 2.73</td><td>Mean Min = 2.40</td></tr>
<tr><td>Ind Max = 4.00</td><td>Ind Max = 4.00</td><td>Ind Min = 2.00</td></tr>
</table>
</td><td>Similar[3]</td></tr>
</table>

<table>
<tr><th>Element of Comparison</th><th>Proposed Device:
Copioumed AAMI 3 Surgical Gown</th><th>Predicate Device[1]:
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K170762</th><th>Comparisons</th></tr>
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(lbs)
ASTM D5587-15Highest Peak</td><td>CD≥10N</td><td>
<table>
<tr><td colspan="2">Test Results (3 Lots)
Mean (min/max)</td><td rowspan="2">Specification</td></tr>
<tr><td>Sleeve</td><td>Body</td></tr>
</table>
Unit = lbs
<table>
<tr><td>Mean = 5.63</td><td>Mean = 5.63</td><td>N/A</td></tr>
<tr><td>Ind Min = 4.67</td><td>Ind Min = 4.67</td><td></td></tr>
<tr><td>Ind Max = 7.90</td><td>Ind Max = 7.90</td><td></td></tr>
</table>
</td><td>Similar[2]</td></tr>
<tr><td>Flammability
(sec)
CPSC, Part 1610</td><td>Class I</td><td>Class I</td><td>Same</td></tr>
<tr><td>Alcohol Repellency
(rating)
NWSP 080.8.R0 (15)</td><td>＞6</td><td>
<table>
<tr><td colspan="2">Test Results (3 Lots)
Mean (min/max)</td><td rowspan="2">Specification</td></tr>
<tr><td>Sleeve</td><td>Body</td></tr>
<tr><td>Mean = 9</td><td>Mean = 9</td><td>Target Mean = 7</td></tr>
<tr><td>Ind Min = 8</td><td>Ind Min = 8</td><td>Mean Min = 6</td></tr>
<tr><td>Ind Max = 9</td><td>Ind Max = 9</td><td>Ind Min = 5</td></tr>
</table>
</td><td>Similar[3]</td></tr>
<tr><td>Hydrostatic Head (cm)
AATCC-127</td><td>≥50cm</td><td>
<table>
<tr><td colspan="2">Test Results (3 Lots)
Mean (min/max)</td><td rowspan="2">Specification</td></tr>
<tr><td>Sleeve</td><td>Body</td></tr>
</table>
</td><td>Similar[2]</td></tr>
</table>

<table>
<tr><th>Element of Comparison</th><th>Proposed Device:
Copioumed AAMI 3 Surgical Gown</th><th>Predicate Device[1]:
Cardinal Health™ Non-Reinforced Surgical Gown
K170762</th><th>Comparisons</th></tr>
<tr><td></td><td></td><td>Unit = cm<table><tr><td>Mean = 89.90</td><td>Mean = 89.90</td><td>Target Mean = 70</td></tr><tr><td>Ind Min = 73.95</td><td>Ind Min = 73.95</td><td>Mean Min = 60</td></tr><tr><td>Ind Max = 100.98</td><td>Ind Max = 100.98</td><td>Ind Min = 53</td></tr></table></td><td></td></tr>
<tr><td>Water Impact (g)
AATCC-42</td><td>≤1.0g</td><td><table><tr><td colspan="2">Test Results (3 Lots)</td><td rowspan="3">Specification</td></tr><tr><td colspan="2">Mean (min/max)</td></tr><tr><td>Sleeve</td><td>Body</td></tr></table>Unit = g<table><tr><td>Mean = 0.10</td><td>Mean = 0.10</td><td>Target Mean = 0.10</td></tr><tr><td>Ind Min = 0.07</td><td>Ind Min = 0.07</td><td>Mean Max = 0.30</td></tr><tr><td>Ind Max = 0.13</td><td>Ind Max = 0.13</td><td>Ind Max = 1.0</td></tr></table></td><td>Similar[2]</td></tr>
</table>

lint generation	Standard Performance: log10 ≈ 3.5–3.6 High Performance log10 ≈ 3.2–3.3	No available data	Different[4]
Seam strength	≥30N	No available data	Different[5]
Performance per AAMI PB70:2012	AAMI Level 3	AAMI Level 3	Same
Contact Durations	Surface, Intact, < 24 hours	Surface, Intact, < 24 hours	Same
Biocompatibility	Under the test conditions,	Under the conditions of each study, the Cardinal Health™ non-reinforced	Same

Element of Comparison	Proposed Device: Copioumed AAMI 3 Surgical Gown	Predicate Device[1]: Cardinal Health™ Non-Reinforced Surgical Gown K170762	Comparisons
	the subject device was shown to be noncytotoxic, non-irritating and non-sensitizing per ISO 10993-5, ISO 10993-23 & ISO 10993-10.	Surgical gown is non-cytotoxic, non-irritating, and non-sensitizing per ISO 10993-1.	

Note 1: Individual Maximum (Ind. Max.): specification allows only one value at this level. Individual minimum (Ind. Min.): specification allows only one value at this level. The mean performance of the proposed device was compared to the mean specification values.
Note 2: The proposed device and predicate device passed the same criteria listed in the standard.
Note 3: We only compared the value of proposed device to the mean value of predicate device for the property. The proposed device and predicate device passed the same criteria listed in the standard.
Note 4: No publicly available lint generation data were identified for the predicate device. Lint generation testing was performed as supplementary characterization of the proposed device. This parameter is not required under AAMI PB70.
Note 5: No publicly available seam strength data were identified for the predicate device. Seam strength testing was performed as physical property characterization of the proposed device.

J. SUMMARY OF NON-CLINICAL DATA

The following performance data were provided to demonstrate the safety and effectiveness:

No.	Standards	Purpose	Acceptance	Results
1.	AATCC 42	Water Resistance	≤1.0G	Pass
2.	AATCC 127	Hydrostatic Pressure	≥50CM H2O	Pass
3.	ANSI/AAMI PB70:2012 AAMI Level 3	Liquid Barrier Performance	Blotter weight gain ≤ 1.0 g Hydrostatic resistance ≥ 50 cm	Pass
4.	NWSP 080.8.R0	Alcohol Repellency (rating)	> 6	Pass
5.	ASTM D3776/D3776M -17	Weight of Woven Fabric	40G±4G	Pass
6.	ASTM D5034 – 9 2017	Grab Tensile, Peak Stretch, and Peak Energy – Nonwovens	MD≥55N CD≥40N	Pass
7.	ISO 10993-7:2008	EO Sterilization Residuals Test	EtO < 4mg ECH < 9 mg	Pass
8.	ASTM D5587-15 (2019)	Standard Test Method for Tearing Strength of Fabrics by the Trapezoid Procedure	MD≥10N CD≥10N	Pass
10.	16 CFR 1610	Standard for the Flammability for Clothing Textiles	Class 1	Pass
11.	ISO 9073-10: 2003	Lint and other particles generation in the dry state	Standard Performance: log10 ≈ 3.5–3.6 High Performance log10 ≈ 3.2–3.3	Pass
12	ASTM D1683	Seam strength	≥30N	Pass

13.	ISO 10993-5:2009	Cytotoxicity	The viability should be ≥ 70% of the blank. And the 50% extract of the test sample should have at least the same or a higher viability than the 100% extract.	Pass
14.	ISO 10993 23:2021	Intracutaneous Irritation Test	Non-irritating	Pass
15.	ISO 10993-10:2010	Maximization Test	Non-sensitizing	Pass
16.	EN ISO 11737-1 (2018/A1:2021)	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products	≤300 CFU/100cm2	Pass

K. The Conclusion drawn from the Non-Clinical tests demonstrates that the subject device Copioumed AAMI 3 Surgical Gown is as safe, as effective, and performs as well as or better than the legally marketed predicate device.