

K251860 Copioumed AAMI 3 Surgical GownFeb 26, 2026
254 days to decisionK251860 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k251860/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Jun 17, 2025
Decision date	Feb 26, 2026
Days to decision	254 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Copioumed International, Inc.
Location	Taipei City, TW
Contact	James Liu
510(k) history	2 submissions · 2 cleared · 2023-2026

REGULATORY CONSULTANT

Consulting firm	Ruscert Technology Co., Ltd.
Contact	Ming-Yie Jan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251860/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026