

K230135 Copioumed Chemotherapy Isolation GownOct 4, 2023
259 days to decisionK230135 · Product code: **FYC** · General Hospital
Source: <https://www.510kdatabase.net/k230135/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Jan 18, 2023
Decision date	Oct 4, 2023
Days to decision	259 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)

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