

**K960999 ISOLATION GOWN**Dec 30, 1996  
293 days to decisionK960999 · Product code: **FYC** · General HospitalSource: <https://www.510kdatabase.net/k960999/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Mar 12, 1996
Decision date	Dec 30, 1996
Days to decision	293 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Copioumed Intl., Inc.</b>
Location	Sparks, NV, US
Contact	JANNA P TUCKER
510(k) history	8 submissions · 8 cleared · 1996-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k960999/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 2, 2026