

K961342 SHOE COVER, NON-STERILEDec 30, 1996
285 days to decisionK961342 · Product code: **FXP** · General HospitalSource: <https://www.510kdatabase.net/k961342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cover, Shoe, Operating-room (FXP)
Date received	Mar 20, 1996
Decision date	Dec 30, 1996
Days to decision	285 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k961342/> 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 July 2, 2026