

K913628 DISPOSABLE SHOE COVEROct 4, 1991
50 days to decisionK913628 · Product code: **FXP** · General Hospital
Source: <https://www.510kdatabase.net/k913628/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cover, Shoe, Operating-room (FXP)
Date received	Aug 15, 1991
Decision date	Oct 4, 1991
Days to decision	50 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Gem Nonwovens, Inc.
Location	Huntsville, AL, US
Contact	JAMES MCLAUGHLIN
510(k) history	2 submissions · 2 cleared · 1991-1991

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k913628/> 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 7, 2026