

K894383 DISPOSABLE SHOE COVERSep 12, 1989
57 days to decisionK894383 · Product code: **FXP** · General HospitalSource: <https://www.510kdatabase.net/k894383/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cover, Shoe, Operating-room (FXP)
Date received	Jul 17, 1989
Decision date	Sep 12, 1989
Days to decision	57 days
Third-party review	No

APPLICANT

Company	American Threshold Industries, Inc.
Location	Walker, MI, US
Contact	ROBERT T BAYER
510(k) history	20 submissions · 20 cleared · 1980-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k894383/>; 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 June 30, 2026