

K971191 FAR-EAST SHOE COVERSJul 10, 1997
101 days to decisionK971191 · Product code: **FXP** · General HospitalSource: <https://www.510kdatabase.net/k971191/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cover, Shoe, Operating-room (FXP)
Date received	Mar 31, 1997
Decision date	Jul 10, 1997
Days to decision	101 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Far East Science & Technology Development Co., Ltd.
Location	Wuhan, CN
Contact	DAVID SONG
510(k) history	3 submissions · 3 cleared · 1997-1997

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