

**K943034 OREX SHOE COVERS**Jan 2, 1995  
189 days to decisionK943034 · Product code: **FXP** · General Hospital  
Source: <https://www.510kdatabase.net/k943034/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cover, Shoe, Operating-room (FXP)
Date received	Jun 27, 1994
Decision date	Jan 2, 1995
Days to decision	189 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Thantex Specialties, Inc.</b>
Location	Norcross, GA, US
Contact	THOMAS B BONNER
510(k) history	21 submissions · 21 cleared · 1994-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943034/> 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 6, 2026