

**K800528 SHIELD PERFECT FIT**Apr 16, 1980  
40 days to decisionK800528 · Product code: **FXP** · General Hospital  
Source: <https://www.510kdatabase.net/k800528/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cover, Shoe, Operating-room (FXP)
Date received	Mar 7, 1980
Decision date	Apr 16, 1980
Days to decision	40 days
Third-party review	No
Other names	DURA-FIT, DISPOS.

**APPLICANT**

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Company	<b>American Convertors Div., American Pharmaseal</b>
Location	Mchenry, IL, US
510(k) history	19 submissions · 19 cleared · 1980-1984

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k800528/>; 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 June 29, 2026