

**K864550 CARETEX SHOE COVERS**Dec 24, 1986  
35 days to decisionK864550 · Product code: **FXP** · General Hospital  
Source: <https://www.510kdatabase.net/k864550/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cover, Shoe, Operating-room (FXP)
Date received	Nov 19, 1986
Decision date	Dec 24, 1986
Days to decision	35 days
Third-party review	No

**APPLICANT**

---

Company	<b>James River Corp.</b>
Location	Walker, MI, US
Contact	RICHARD L DAVIS
510(k) history	15 submissions · 14 cleared · 1983-1989

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k864550/>, 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 7, 2026