

**K864479 CARETEX ISOLUTION GOWNS**Dec 9, 1986  
26 days to decisionK864479 · Product code: **FYC** · General HospitalSource: <https://www.510kdatabase.net/k864479/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Nov 13, 1986
Decision date	Dec 9, 1986
Days to decision	26 days
Third-party review	No

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k864479/>; 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