

**K963595 SERAGARD VASCULAR ACCESS DEVICE**Jan 6, 1997  
119 days to decisionK963595 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k963595/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 9, 1996
Decision date	Jan 6, 1997
Days to decision	119 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Cutting Edge Technologies, Inc.</b>
Location	Malvern, PA, US
Contact	WALTER L YATES
510(k) history	2 submissions · 2 cleared · 1995-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k963595/> 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 5, 2026