

K994216 PLASTIC PORT IMPLANTABLE VENOUS ACCESS SYSTEMJan 27, 2000
43 days to decisionK994216 · Product code: **LJT** · General Hospital
Source: <https://www.510kdatabase.net/k994216/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Port & Catheter, Implanted, Subcutaneous, Intravascular (LJT)
Date received	Dec 15, 1999
Decision date	Jan 27, 2000
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sims Deltec, Inc.
Location	St. Paul, MN, US
Contact	LISA STONE
510(k) history	32 submissions · 32 cleared · 1995-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k994216/> Data sourced from FDA 510(k) public records (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. - Generated July 4, 2026