

**K955046 SOFT VENOUS RESERVOIR**Jan 11, 1996  
69 days to decisionK955046 · Product code: **DTN** · CardiovascularSource: <https://www.510kdatabase.net/k955046/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Nov 3, 1995
Decision date	Jan 11, 1996
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gish Biomedical, Inc.</b>
Location	Mchenry, IL, US
Contact	DEBRA J KRIDNER
510(k) history	75 submissions · 75 cleared · 1983-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k955046/> 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 May 26, 2026