

**K871596 IONESCU-SHILEY PERICARDIAL XENOGRAFT (ISU)**Jun 15, 1987  
52 days to decisionK871596 · Product code: **DTJ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k871596/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Holder, Heart-valve, Prosthesis (DTJ)
Date received	Apr 24, 1987
Decision date	Jun 15, 1987
Days to decision	52 days
Third-party review	No

**APPLICANT**

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Company	<b>Shiley, Inc.</b>
Location	Mchenry, IL, US
Contact	RADINE POBUDA
510(k) history	174 submissions · 174 cleared · 1976-1993

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k871596/>; 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