

**K991027 BI-DIRECTIONAL TUNNELER**Apr 22, 1999  
24 days to decisionK991027 · Product code: **DSY** · CardiovascularSource: <https://www.510kdatabase.net/k991027/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Mar 29, 1999
Decision date	Apr 22, 1999
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Impra, Inc.</b>
Location	Mchenry, IL, US
Contact	KRISTI M KISTNER
510(k) history	29 submissions · 24 cleared · 1979-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k991027/> 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