

**K980578 INNERDYNE RADially EXPANDING VASCULAR ACCESS SYSTEM (HEPARIN COATED)**Sep 11, 1998  
206 days to decisionK980578 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k980578/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Feb 17, 1998
Decision date	Sep 11, 1998
Days to decision	206 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Innerdyne, Inc.</b>
Location	Salt Lake City, UT, US
Contact	RICK GAYKOWSKI
510(k) history	12 submissions · 12 cleared · 1995-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k980578/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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