

**K031583 MODIFICATION TO IVS INTRODUCER SET, MODEL 1003**Jun 16, 2003  
26 days to decisionK031583 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k031583/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	May 21, 2003
Decision date	Jun 16, 2003
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Integrated Vascular Systems, Inc.</b>
Location	Sunnyvale, CA, US
Contact	SUSAN TURNER
510(k) history	3 submissions · 3 cleared · 2002-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031583/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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