

**K010913 VYGON SPLIT CANNULA INTRODUCER**Sep 28, 2001  
185 days to decisionK010913 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k010913/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Mar 27, 2001
Decision date	Sep 28, 2001
Days to decision	185 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Vygon Corp.</b>
Location	East Rutherford, NJ, US
Contact	ROBERT SCHIFF
510(k) history	48 submissions · 46 cleared · 1985-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010913/> 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