

**K102925 NEXGEN EXPANDABLE CATHETER**Nov 10, 2011  
402 days to decisionK102925 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k102925/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Oct 4, 2010
Decision date	Nov 10, 2011
Days to decision	402 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nexgen Medical Systems, Inc.</b>
Location	Reno, NV, US
Contact	CRAIG PAGAN
510(k) history	4 submissions · 4 cleared · 2009-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k102925/> 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 June 18, 2026