

**K041708 ENPATH SAFETY INTRODUCER**Nov 30, 2004  
160 days to decisionK041708 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k041708/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jun 23, 2004
Decision date	Nov 30, 2004
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Enpath Medical Incorporated</b>
Location	Minneapolis, MN, US
Contact	KARYL HASKELL
510(k) history	2 submissions · 2 cleared · 2004-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k041708/> 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 July 2, 2026