

**K082847 PINNACLE ROII INTRODUCER SHEATH**Oct 29, 2008  
30 days to decisionK082847 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k082847/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Sep 29, 2008
Decision date	Oct 29, 2008
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Terumo Medical Corp.</b>
Location	Elkton, MD, US
Contact	MARK UNTERREINER
510(k) history	143 submissions · 143 cleared · 1980-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082847/> 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 27, 2026