

**K082644 GLIDESHEATH**Sep 18, 2008  
7 days to decisionK082644 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k082644/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Sep 11, 2008
Decision date	Sep 18, 2008
Days to decision	7 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Terumo Medical Corp.</b>
Location	Elkton, MD, US
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/k082644/>; 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