

**K081046 PINNACLE DESTINATION PERIPHERAL GUIDING SHEATH**

May 21, 2008  
37 days to decision

K081046 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k081046/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Apr 14, 2008
Decision date	May 21, 2008
Days to decision	37 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/k081046/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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