

**K062446 MODIFICATION TO PINNACLE ROII HIFLOW
INTRODUCER SHEATH**Oct 23, 2006
62 days to decisionK062446 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k062446/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Aug 22, 2006
Decision date	Oct 23, 2006
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k062446/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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