

**K012489 MODIFICATION TO: X-SEPT TRANSSEPTAL SHEATH  
AND TRANSITION CATHETER (WITH DILATOR), MODELS  
PL-12-12-09, PL-12-12-10**Aug 30, 2001  
27 days to decisionK012489 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k012489/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Aug 3, 2001
Decision date	Aug 30, 2001
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Appriva Medical, Inc.</b>
Location	Sunnyvale, CA, US
Contact	MICHAEL KOLBER
510(k) history	2 submissions · 2 cleared · 2001-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012489/> 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 3, 2026