

**K000313 TEARAWAY INTRODUCER SHEATH**Jun 16, 2000  
136 days to decisionK000313 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k000313/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Feb 1, 2000
Decision date	Jun 16, 2000
Days to decision	136 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xentek Medical, Inc.</b>
Location	Athens, TX, US
Contact	JIM EDDINGS
510(k) history	2 submissions · 2 cleared · 2000-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k000313/> 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