

**K153771 TXM Guiding Sheath**Sep 13, 2016  
258 days to decisionK153771 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k153771/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Dec 30, 2015
Decision date	Sep 13, 2016
Days to decision	258 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Texasmedical Technologies, Inc.</b>
Location	El Paso, TX, US
Contact	Aaron Chiu
510(k) history	7 submissions · 7 cleared · 2015-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153771/> 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 31, 2026