

**K173399 Endophys Pressure Sensing Sheath Kit- 8F**Nov 30, 2017  
30 days to decisionK173399 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k173399/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Oct 31, 2017
Decision date	Nov 30, 2017
Days to decision	30 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Endophys Holdings, LLC</b>
Location	Dallas, TX, US
Contact	Phillip Purdy
510(k) history	4 submissions · 4 cleared · 2016-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173399/> 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 June 28, 2026