

**K180620 Endophys Pressure Sensing Sheath Kit**Oct 12, 2018  
217 days to decisionK180620 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k180620/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Mar 9, 2018
Decision date	Oct 12, 2018
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Sachs &amp; Associates, Inc.</b>
Contact	Gregory W. Sachs

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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