

K190098 Endophys Pressure Sensing SheathMar 7, 2019
44 days to decisionK190098 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k190098/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Jan 22, 2019
Decision date	Mar 7, 2019
Days to decision	44 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Sachs & Associates, Inc.
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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