

**K190628 FlexSeal Introducer Sheath with Hydrophilic Coating**May 30, 2019  
79 days to decisionK190628 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k190628/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Mar 12, 2019
Decision date	May 30, 2019
Days to decision	79 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Freudenberg Medical Mis, Inc.</b>
Location	Jeffersonville, IN, US
Contact	Larry Bender
510(k) history	1 submissions · 1 cleared · 2019-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Mark Job

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190628/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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