

**K152310 HeartLight Deflectable Sheath**Feb 24, 2016  
194 days to decisionK152310 · Product code: **DRA** · Cardiovascular  
Source: <https://www.510kdatabase.net/k152310/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Steerable (DRA)
Date received	Aug 14, 2015
Decision date	Feb 24, 2016
Days to decision	194 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cardiofocus, Inc.</b>
Location	Norton, MA, US
Contact	Seema Paliwal
510(k) history	5 submissions · 5 cleared · 2000-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152310/> 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 3, 2026