FDA 510(k) Premarket Notification

K152310 HeartLight Deflectable Sheath

CLEARED

Feb 24, 2016
194 days to decision

K152310 · Product code: **DRA** · Cardiovascular
Source: https://www.510kdatabase.net/k152310/

SUBMISSION DETAILS

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

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