

K123591 FLEXCATH ADVANCE STEERABLE SHEATH (12 FRENCH)

Dec 27, 2012
36 days to decision

K123591 · Product code: **DRA** · Cardiovascular
Source: <https://www.510kdatabase.net/k123591/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Steerable (DRA)
Date received	Nov 21, 2012
Decision date	Dec 27, 2012
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Cryocath, LP
Location	Kirkland, CA
Contact	VANESSA WARE
510(k) history	6 submissions · 6 cleared · 2010-2020

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k123591/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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