

K112541 Z FLEX-270TM STEERABLE SHEATHFeb 7, 2012
159 days to decisionK112541 · Product code: **DRA** · Cardiovascular
Source: <https://www.510kdatabase.net/k112541/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Steerable (DRA)
Date received	Sep 1, 2011
Decision date	Feb 7, 2012
Days to decision	159 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Great Batch Medical
Location	Plymouth, MN, US
Contact	SARA BAKKER
510(k) history	10 submissions · 10 cleared · 2009-2018

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