

K130559 MOBICATH BI-DIRECTIONAL GUIDING SHEATHMay 24, 2013
81 days to decisionK130559 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k130559/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Mar 4, 2013
Decision date	May 24, 2013
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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