

**K101784 MOBICATH BI-DIRECTIONAL GUIDING SHEATH
MODEL 1000182-XXX**Nov 26, 2010
154 days to decisionK101784 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k101784/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jun 25, 2010
Decision date	Nov 26, 2010
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101784/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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