FDA 510(k) Premarket Notification

K101784 MOBICATH BI-DIRECTIONAL GUIDING SHEATH MODEL 1000182-XXX

CLEARED

Nov 26, 2010
154 days to decision

K101784 · 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	Pymouth, MN, US
Contact	Kristi Fox
510(k) history	10 submissions · 10 cleared · 2009-2018