FDA 510(k) Premarket Notification

K111644 MOBICATH TRANSSEPTAL NEEDLE

CLEARED

Oct 3, 2011
112 days to decision

K111644 · Product code: **DRC** · Cardiovascular
Source: https://www.510kdatabase.net/k111644/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Trocar (DRC)
Date received	Jun 13, 2011
Decision date	Oct 3, 2011
Days to decision	112 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