FDA 510(k) Premarket Notification

K102540 PTFE PORTABLE INTRODUCER

CLEARED

Nov 16, 2010
74 days to decision

K102540 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k102540/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Sep 3, 2010
Decision date	Nov 16, 2010
Days to decision	74 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