

K102540 PTFE PORTABLE INTRODUCERNov 16, 2010
74 days to decisionK102540 · 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	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/k102540/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 30, 2026