

K093023 PTFE PEELABLE INTRODUCEROct 29, 2009
30 days to decisionK093023 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k093023/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Sep 29, 2009
Decision date	Oct 29, 2009
Days to decision	30 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

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