

K093232 OPTISEAL ENPATH VALVED PTFE PEELABLE INTRODUCER

Mar 15, 2010
152 days to decision

K093232 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k093232/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Oct 14, 2009
Decision date	Mar 15, 2010
Days to decision	152 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Great Batch Medical
Location	Plymouth, MN, US
Contact	SHANNON SPRINGER
510(k) history	10 submissions · 10 cleared · 2009-2018

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k093232/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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