

K081394 PTFE INTERLOCK PEELABLE INTRODUCERSSep 15, 2008
119 days to decisionK081394 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k081394/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	May 19, 2008
Decision date	Sep 15, 2008
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Enpath Medical, Inc.
Location	Minneapolis, MN, US
Contact	SHANNON SPRINGER
510(k) history	5 submissions · 5 cleared · 2006-2008

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