

K153246 PTFE Super Sheath Introducer 2.1Feb 12, 2016
95 days to decisionK153246 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k153246/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Nov 9, 2015
Decision date	Feb 12, 2016
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medcomp (Medical Components, Inc.)
Location	Harleysville, PA, US
Contact	COURTNEY NIX
510(k) history	6 submissions · 6 cleared · 2013-2017

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