

K002054 X-SEPT TRANSSEPTAL SHEATH AND TRANSITION CATHETER, MODEL MV-03-09-90, MV-03-10-90, MV-03-11-90, MV-03-09-120, MV-03-10-1Feb 16, 2001
225 days to decisionK002054 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k002054/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jul 6, 2000
Decision date	Feb 16, 2001
Days to decision	225 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Appriva Medical, Inc.
Location	Sunnyvale, CA, US
Contact	MICHAEL KOLBER
510(k) history	2 submissions · 2 cleared · 2001-2001

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