CLEARED

K012489 MODIFICATION TO: X-SEPT TRANSSEPTAL SHEALTH AND TRANSITION CATHETER (WITH DILATOR), MODELS PL-12-12-09, PL-12-12-10

Aug 30, 2001
27 days to decision

K012489 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k012489/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Aug 3, 2001
Decision date	Aug 30, 2001
Days to decision	27 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