FDA 510(k) Premarket Notification

K061000 EVOLUTION MECHANICAL DILATOR SHEATH SET MODELS-LR-EVN-7.0, LR-EVN-9.0

CLEARED

May 10, 2006
29 days to decision

K061000 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k061000/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Apr 11, 2006
Decision date	May 10, 2006
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cook Vascular, Inc.**
Location	Leechburg, PA, US
Contact	JIM FERGUSON, JR
510(k) history	12 submissions · 12 cleared · 2001-2014