

**K061000 EVOLUTION MECHANICAL DILATOR SHEATH SET
MODELS-LR-EVN-7.0, LR-EVN-9.0**May 10, 2006
29 days to decisionK061000 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061000/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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