

K142301 Evolution Mechanical Dilator Sheath Set, Evolution Shortie Mechanical Dilator Sheath Set, SteadySheath Evolution Tissue Stabilization Sheath, SteadySheath Evolution Shortie Tissue Stabilization SheathNov 12, 2014
86 days to decisionK142301 · Product code: **DRE** · Cardiovascular
Source: <https://www.510kdatabase.net/k142301/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Aug 18, 2014
Decision date	Nov 12, 2014
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Vascular, Inc.
Location	Leechburg, PA, US
Contact	Thomas J. Kardos
510(k) history	12 submissions · 12 cleared · 2001-2014

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