

**K253616 ProtekDilate Vascular Access Kit**Dec 19, 2025  
31 days to decisionK253616 · Product code: **DRE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k253616/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Nov 18, 2025
Decision date	Dec 19, 2025
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sorin Group Italia S.R.L.</b>
Location	Mirandola, IT
Contact	Luigi Vecchi
510(k) history	61 submissions · 61 cleared · 1995-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>LivaNova USA, Inc.</b>
Contact	Jennifer Houck

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253616/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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