

**K905416 VESSEL DILATOR**Mar 25, 1991  
111 days to decisionK905416 · Product code: **DRE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k905416/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Dec 4, 1990
Decision date	Mar 25, 1991
Days to decision	111 days
Third-party review	No

**APPLICANT**

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Company	<b>The R Group</b>
Location	Gainesvilles, FL, US
Contact	MARK J KAHN
510(k) history	4 submissions · 4 cleared · 1991-1991

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k905416/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated July 6, 2026