

**K801113 DILATOR, VESSEL, FOR PERC. CATHETER.**Jul 28, 1980  
77 days to decisionK801113 · Product code: **DRE** · CardiovascularSource: <https://www.510kdatabase.net/k801113/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	May 12, 1980
Decision date	Jul 28, 1980
Days to decision	77 days
Third-party review	No

**APPLICANT**

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Company	<b>Alva Medical, Inc.</b>
Location	Mchenry, IL, US
510(k) history	2 submissions · 2 cleared · 1980-1980

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k801113/> 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 9, 2026