

**K860161 HEART CATHETERIZATION TRAY**May 2, 1986  
106 days to decisionK860161 · Product code: **DRE** · CardiovascularSource: <https://www.510kdatabase.net/k860161/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Jan 16, 1986
Decision date	May 2, 1986
Days to decision	106 days
Third-party review	No

**APPLICANT**

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Company	<b>Medical Design Concepts, Inc.</b>
Location	Carlsbad, CA, US
Contact	RONALD BERTANZI
510(k) history	2 submissions · 2 cleared · 1986-1986

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k860161/>; 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 7, 2026