

**K962829 HARMAC BALLOON ANGIOGRAPHIC CATHETER**Oct 16, 1997  
475 days to decisionK962829 · Product code: **DQO** · CardiovascularSource: <https://www.510kdatabase.net/k962829/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Jun 28, 1996
Decision date	Oct 16, 1997
Days to decision	475 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Harmac Medical Products, Inc.</b>
Location	Buffalo, NY, US
Contact	JOSEPH M KNOIECZNY
510(k) history	8 submissions · 8 cleared · 1995-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k962829/> 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 2, 2026