

**K924712 ROTABLATOR ROTATIONAL ANGIOPLASTY SYSTEM**Dec 8, 1992  
81 days to decisionK924712 · Product code: **MCW** · CardiovascularSource: <https://www.510kdatabase.net/k924712/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Sep 18, 1992
Decision date	Dec 8, 1992
Days to decision	81 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Hearing Tech, Inc.</b>
Location	Minnetonka, MN, US
Contact	LOUISE C MYERS
510(k) history	11 submissions · 11 cleared · 1985-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k924712/> 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 5, 2026