

K953997 ROTABLATOR ROTATIONAL ANGIOPLASTYDec 22, 1995
120 days to decisionK953997 · Product code: **MCW** · CardiovascularSource: <https://www.510kdatabase.net/k953997/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Aug 24, 1995
Decision date	Dec 22, 1995
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Heart Technology Mfg., Inc.
Location	Redmond, WA, US
Contact	DIANE JOHNSON
510(k) history	3 submissions · 3 cleared · 1995-1996

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