

**K021641 XTD THROMBECTOMY CATHETER, XX CM**Jul 26, 2002  
67 days to decisionK021641 · Product code: **QEW** · CardiovascularSource: <https://www.510kdatabase.net/k021641/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	May 20, 2002
Decision date	Jul 26, 2002
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xtrak Medical, Inc.</b>
Location	Hopkinton, MA, US
Contact	DEBBIE IAMPIETRO
510(k) history	3 submissions · 3 cleared · 2002-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k021641/> 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 3, 2026