

**K021096 X-SIZER CATHETER SYSTEM**Sep 8, 2004  
888 days to decisionK021096 · Product code: **MCW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k021096/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Apr 4, 2002
Decision date	Sep 8, 2004
Days to decision	888 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Ev3 Corporation</b>
Location	Plymouth, MN, US
Contact	JILL MUNSINGER
510(k) history	5 submissions · 4 cleared · 2003-2005

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k021096/> 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 June 30, 2026