

**K061912 FUSION**Aug 1, 2006  
26 days to decisionK061912 · Product code: **INI** · Physical MedicineSource: <https://www.510kdatabase.net/k061912/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vehicle, Motorized 3-wheeled (INI)
Date received	Jul 6, 2006
Decision date	Aug 1, 2006
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Burke, Inc.</b>
Location	Mchenry, IL, US
Contact	DUWAYNE E KRAMER, JR.
Website	<a href="http://www.burke.com">http://www.burke.com</a>
510(k) history	7 submissions · 7 cleared · 1984-2006

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061912/> 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 29, 2026