FDA 510(k) Premarket Notification

K061912 FUSION

CLEARED

Aug 1, 2006
26 days to decision

K061912 · Product code: **INI** · Physical Medicine
Source: https://www.510kdatabase.net/k061912/

SUBMISSION DETAILS

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

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