

K041063 SMARTWAVE MS 2000Dec 1, 2004
222 days to decisionK041063 · Product code: **IPF** · Physical Medicine
Source: <https://www.510kdatabase.net/k041063/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Apr 23, 2004
Decision date	Dec 1, 2004
Days to decision	222 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Newwave Medical, LLC
Location	Plano, TX, US
Contact	ROBERT ARMSTRONG
510(k) history	3 submissions · 3 cleared · 1999-2004

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