

**K945803 THERMAFLEX, MODEL SD 55 C.P.M.H.**May 11, 1995  
164 days to decisionK945803 · Product code: **JFA** · Physical Medicine  
Source: <https://www.510kdatabase.net/k945803/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Exerciser, Finger, Powered (JFA)
Date received	Nov 28, 1994
Decision date	May 11, 1995
Days to decision	164 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Burke Neutech, Inc.</b>
Location	Largo, FL, US
Contact	ROBERT E BURKE
510(k) history	7 submissions · 6 cleared · 1993-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945803/> 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