

**K071050 GAME READY PROFESSIONAL THERAPY SYSTEM,  
MODEL 550100, GAME READY PRE-PROGRAMMED  
PROFESSIONAL THERAPY SYSTEM**Jun 29, 2007  
77 days to decisionK071050 · Product code: **IRP** · Physical Medicine  
Source: <https://www.510kdatabase.net/k071050/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Apr 13, 2007
Decision date	Jun 29, 2007
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Coolsystems, Inc.</b>
Location	Berkeley, CA, US
Contact	MARIANNE BALDWIN
510(k) history	2 submissions · 2 cleared · 2007-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k071050/> 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 26, 2026