

**K050507 SMARTECH, MODEL HOLI I**Jul 7, 2005  
129 days to decisionK050507 · Product code: **INI** · Physical Medicine  
Source: <https://www.510kdatabase.net/k050507/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vehicle, Motorized 3-wheeled (INI)
Date received	Feb 28, 2005
Decision date	Jul 7, 2005
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cycling and Health Tech. Industry R&amp;D Center</b>
Location	Taichung, TW
Contact	CHANG WAN-LAN
510(k) history	5 submissions · 5 cleared · 2004-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050507/> 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