

**K160835 Titan 3W**Feb 2, 2017  
314 days to decisionK160835 · Product code: **INI** · Physical Medicine  
Source: <https://www.510kdatabase.net/k160835/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vehicle, Motorized 3-wheeled (INI)
Date received	Mar 25, 2016
Decision date	Feb 2, 2017
Days to decision	314 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tzora Active Systems , Ltd.</b>
Location	Kibbutz Tzora, IL
Contact	Adi Shemer
510(k) history	5 submissions · 5 cleared · 2001-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160835/> 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 May 30, 2026