

**K190015 Ballancer Gold, 1212**Mar 25, 2019  
81 days to decisionK190015 · Product code: **IRP** · Physical Medicine  
Source: <https://www.510kdatabase.net/k190015/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Jan 3, 2019
Decision date	Mar 25, 2019
Days to decision	81 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Mego Afek AC , Ltd.</b>
Location	Kfar Saba, IL
Contact	Reuven Yunger
510(k) history	17 submissions · 17 cleared · 2008-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190015/> 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 27, 2026