

**K214053 Amputee Garment for use with Lympha Press Optimal Plus**Apr 14, 2022  
108 days to decisionK214053 · Product code: **JOW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k214053/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Dec 27, 2021
Decision date	Apr 14, 2022
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Ilan Sharon MD Consultant</b>
Contact	Ilan Sharon

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k214053/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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