

K230385 Ballancer Platinum (1222)Apr 4, 2023
49 days to decisionK230385 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k230385/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Feb 14, 2023
Decision date	Apr 4, 2023
Days to decision	49 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Mego Afek
Location	Walker, MI, US
Contact	Yunger Reuven
510(k) history	5 submissions · 5 cleared · 1981-2023

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