

K254267 NanoPress 760A-BT (760A-BT)

Feb 24, 2026
56 days to decision

K254267 · Product code: **JOW** · Cardiovascular
Source: <https://www.510kdatabase.net/k254267/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Dec 30, 2025
Decision date	Feb 24, 2026
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Mego Afek , Ltd.
Location	Kibbutz Afek, IL
Contact	Reuven Yunger
Website	https://www.megoafek.com
510(k) history	1 submissions · 1 cleared · 2026-2026

Mego Afek, Ltd. is an Israeli medical device manufacturer specializing in pneumatic compression therapy systems. Founded in the mid-1960s at Kibbutz Afek in northern Israel, the company develops and produces dynamic compression devices for circulatory enhancement and therapeutic applications. The company has received FDA 510(k) clearance from total submission. Mego Afek focuses exclusively on Cardiovascular devices, with its latest FDA clearance in 2026. The company maintains active regulatory status and holds quality certifications including ISO 13485:2016 and compliance...

REGULATORY CONSULTANT

Consulting firm	Ilan Sharon MD Consultant
Contact	Ilan Sharon

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