

K242754 ZT Clinic (MG675A)May 5, 2025
235 days to decisionK242754 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k242754/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Sep 12, 2024
Decision date	May 5, 2025
Days to decision	235 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ZT Cube (ZC3) (MG465A); Z-ONE (MG455A)

APPLICANT

Company	Zamar Medical D.O.O.
Location	Vrsar, HR
Contact	Gianmarco Zanotti
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Isemed S.R.L.
Contact	Guido Bonapace

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242754/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026