

K210166 Omnispec ED1000Jan 27, 2023
736 days to decisionK210166 · Product code: **ISA** · Physical Medicine
Source: <https://www.510kdatabase.net/k210166/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Therapeutic, Electric (ISA)
Date received	Jan 21, 2021
Decision date	Jan 27, 2023
Days to decision	736 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medispec, Ltd.
Location	Germantown, MD, US
Contact	Avner Spector
510(k) history	4 submissions · 4 cleared · 1998-2023

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