

K210284 ManaSportApr 26, 2022
448 days to decisionK210284 · Product code: **IMI** · Physical Medicine
Source: <https://www.510kdatabase.net/k210284/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ultrasonic Diathermy For Use In Applying Therapeutic Deep Heat (IMI)
Date received	Feb 2, 2021
Decision date	Apr 26, 2022
Days to decision	448 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Manamed, Inc.
Location	Costa Mesa, CA, US
Contact	Trevor Theriot
510(k) history	7 submissions · 7 cleared · 2016-2023

REGULATORY CONSULTANT

Consulting firm	Jkh USA, LLC
Contact	Bill Quanqin Dai

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

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