FDA 510(k) Premarket Notification

K240788 Ultrasound Stimulator

CLEARED

Jun 4, 2025
439 days to decision

K240788 · Product code: **IMI** · Physical Medicine
Source: https://www.510kdatabase.net/k240788/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ultrasonic Diathermy For Use In Applying Therapeutic Deep Heat (IMI)
Date received	Mar 22, 2024
Decision date	Jun 4, 2025
Days to decision	439 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Jkh Health Co., Ltd.**
Location	Shenzhen, CN
Contact	Pu Jiang
510(k) history	10 submissions · 10 cleared · 2016-2025

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