

K251622 Hand Massager (SM004D)Jan 28, 2026
245 days to decisionK251622 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k251622/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	May 28, 2025
Decision date	Jan 28, 2026
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ningbo Zhenhai Yihao Electronic Technology Co., Ltd.
Location	Ningbo, CN
Contact	Honglie Wang
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Microkn Medical Technology Service (Shanghai) Co., Ltd.
Contact	Owen He

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

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