

K244041 Ultrasound Therapy Workstation (XMS-UET2)Oct 7, 2025
281 days to decisionK244041 · Product code: **IMG** · Physical Medicine
Source: <https://www.510kdatabase.net/k244041/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Ultrasound And Muscle, For Use In Applying Therapeutic Deep Heat (IMG)
Date received	Dec 30, 2024
Decision date	Oct 7, 2025
Days to decision	281 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xemis Medical Technology (Shenzhen) Co., Ltd.
Location	Shenzhen, CN
Contact	Yongfen Yang
510(k) history	2 submissions · 2 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Chonconn Consulting Co., Ltd.
Contact	Jie Yang

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/k244041/> 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 14, 2026