FDA 510(k) Premarket Notification

CLEARED

K260111 Palmtop Ultrasound Diagnostic System (MT10P/MT10)

May 14, 2026
120 days to decision

K260111 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k260111/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jan 14, 2026
Decision date	May 14, 2026
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mytech Intelligence (Shenzhen) Co., Ltd.**
Location	Shenzhen, CN
Contact	Xulei Shi
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Dongguan Woer Biotechnology Consulting Co., Ltd.**
Contact	Amos Zou

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