

K261288 Handheld Ultrasound Scanner

Jul 30, 2026
101 days to decision

K261288 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k261288/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 20, 2026
Decision date	Jul 30, 2026
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	IMGFAX CO., LTD.
Location	Foshan, CN
Contact	Chen Salon
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.net
Device record: <https://www.510kdatabase.net/k261288/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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