

K250791 ASUS Ultrasound Imaging System (LU800 series)Dec 4, 2025
265 days to decisionK250791 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k250791/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Mar 14, 2025
Decision date	Dec 4, 2025
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Asustek Computer, Inc.
Location	Taipei, TW
Contact	Wu Andy
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250791/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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