

K243226 Ultrasound Imaging System (LU700 Series)May 8, 2025
212 days to decisionK243226 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k243226/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Oct 8, 2024
Decision date	May 8, 2025
Days to decision	212 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Ultrasound Imaging System (128 Series); Ultrasound Imaging System (LX Series)

APPLICANT

Company	Leltek, Inc.
Location	New Taipei City, TW
Contact	Paul Chang
510(k) history	5 submissions · 5 cleared · 2020-2025

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