

K210432 LELTEK Ultrasound Imaging System (Model: LU700 Series)Nov 3, 2021
264 days to decisionK210432 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k210432/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 12, 2021
Decision date	Nov 3, 2021
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210432/> 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 26, 2026