

K222365 Leltek Ultrasound Imaging System (Model: LU700 Series)

Oct 25, 2022
82 days to decision

K222365 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k222365/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 4, 2022
Decision date	Oct 25, 2022
Days to decision	82 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k222365/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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