

K241161 Ultrasound Imaging System (LK128L)Sep 11, 2024
138 days to decisionK241161 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k241161/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 26, 2024
Decision date	Sep 11, 2024
Days to decision	138 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Ultrasound Imaging System (LK128LH); Ultrasound Imaging System (LK128C); Ultrasound Imaging System (LK128M); Ultrasound Imaging System (LK128PA); Ultrasound Imaging System (LK128E); Ultrasound Imaging System (LU700C); Ultrasound Imaging System (LU700L); Ultrasound Imaging System (LU710L); Ultrasound Imaging System (LU710LH); Ultrasound Imaging System (LU710C); Ultrasound Imaging System (LU710M); Ultrasound Imaging System (LU710PA); Ultrasound Imaging

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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