

K191235 Leltek Ultrasound Imaging SystemFeb 12, 2020
280 days to decisionK191235 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k191235/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	May 8, 2019
Decision date	Feb 12, 2020
Days to decision	280 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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