

K210154 Labat series Diagnostic Ultrasound SystemJul 30, 2021
190 days to decisionK210154 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k210154/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jan 21, 2021
Decision date	Jul 30, 2021
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Wisonic Medical Technology Co. , Ltd.
Location	Shenzhen, CN
Contact	Jiang Xiaosan
510(k) history	7 submissions · 7 cleared · 2018-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210154/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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