

K233439 HD60 Series Ultrasound Diagnostic SystemFeb 21, 2024
128 days to decisionK233439 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k233439/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Oct 16, 2023
Decision date	Feb 21, 2024
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Qingdao Hisense Medical Equipment Co., Ltd.
Location	Qingdao, CN
Contact	Yalan Wu
510(k) history	9 submissions · 9 cleared · 2015-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233439/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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