

K250228 eHertz Functional Series Diagnostic Ultrasound System (eHertz C, eHertz E, eHertz R, eHertz S)

Apr 23, 2025
86 days to decision

K250228 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k250228/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jan 27, 2025
Decision date	Apr 23, 2025
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Esonic Technology (Wuhan) Co., Ltd.
Location	Wuhan, CN
Contact	Souquet Jacques
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k250228/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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