

K231659 MS55 Plus Digital Color Doppler Ultrasound System (MS55)

Feb 15, 2024
253 days to decision

K231659 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k231659/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jun 7, 2023
Decision date	Feb 15, 2024
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	P25 Expert Digital Color Doppler Ultrasound System (P25 Expert); P12 Plus Digital Color Doppler Ultrasound System (P12 Plus); P11 Plus Portable Digital Color Doppler Ultrasound System (P11 Plus); P9 Plus Ultrasound Diagnostic System (P9 Plus); P3 Plus Ultrasound Diagnostic System (P3 Plus)

APPLICANT

Company	Medisono
Location	Doral, FL, US
Contact	Jorge Millan
510(k) history	1 submissions · 1 cleared · 2024-2024

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Device record: <https://www.510kdatabase.net/k231659/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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