

K234153 EdgeLife Handheld Wireless Ultrasound System (E8200)

Sep 18, 2024
264 days to decision

K234153 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k234153/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 29, 2023
Decision date	Sep 18, 2024
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	EdgeLife Handheld Wireless Ultrasound System (E8220)

APPLICANT

Company	Edgelife Technologies, LLC
Location	Miami, FL, US
Contact	Quinn Place
510(k) history	1 submissions · 1 cleared · 2024-2024

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k234153/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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