FDA 510(k) Premarket Notification

K181685 Vivid E80, Vivid E90, Vivid E95

CLEARED

Oct 25, 2018
121 days to decision

K181685 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k181685/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jun 26, 2018
Decision date	Oct 25, 2018
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**GE Medical Systems Ultrasound and Primary Care Diagnostics**
Location	Wauwatosa, WI, US
Contact	Tracey Ortiz
510(k) history	64 submissions · 64 cleared · 2015-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k181685/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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