

K221148 Vivid iqJul 18, 2022
89 days to decisionK221148 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k221148/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received | Apr 20, 2022 |
| Decision date | Jul 18, 2022 |
| Days to decision | 89 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC |
| Location | Wauwatosa, WI, US |
| Contact | Lee Bush |
| 510(k) history | 14 submissions · 14 cleared · 2016-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221148/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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