

K233692 Voluson Signature 20, Voluson Signature 18Mar 7, 2024
111 days to decisionK233692 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k233692/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received | Nov 17, 2023 |
| Decision date | Mar 7, 2024 |
| Days to decision | 111 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233692/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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