

K210438 Versana PremierSep 10, 2021
210 days to decisionK210438 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k210438/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received | Feb 12, 2021 |
| Decision date | Sep 10, 2021 |
| Days to decision | 210 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 | Tracey Ortiz |
| 510(k) history | 64 submissions · 64 cleared · 2015-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210438/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026