

K200138 Versana PremierJul 1, 2020
162 days to decisionK200138 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k200138/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jan 21, 2020
Decision date	Jul 1, 2020
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ge Medical Systems Ultrasound And
Location	Wauwatosa, WI, US
Contact	Tracey Ortiz
510(k) history	5 submissions · 5 cleared · 2020-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200138/> 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 27, 2026