

K223407 Versana EssentialFeb 15, 2023
98 days to decisionK223407 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k223407/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 9, 2022
Decision date	Feb 15, 2023
Days to decision	98 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	Bush Lee
510(k) history	64 submissions · 64 cleared · 2015-2026

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