

K200998 Versana ActiveJun 11, 2020
56 days to decisionK200998 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k200998/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 16, 2020
Decision date	Jun 11, 2020
Days to decision	56 days
Third-party review	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

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