

K191792 Versana BalanceAug 9, 2019
37 days to decisionK191792 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k191792/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 3, 2019
Decision date	Aug 9, 2019
Days to decision	37 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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