

K201828 Voluson SWIFT, Voluson SWIFT+Oct 11, 2020
101 days to decisionK201828 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k201828/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 2, 2020
Decision date	Oct 11, 2020
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	GE Medical Systems Ultrasound and Primary Care Diagnostics
Location	Wauwatosa, WI, US
Contact	Bryan Behn
510(k) history	64 submissions · 64 cleared · 2015-2026

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