

K181934 Vivid T8, Vivid T9Nov 6, 2018
110 days to decisionK181934 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k181934/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 19, 2018
Decision date	Nov 6, 2018
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC
Location	Wauwatosa, WI, US
Contact	Tracey Ortiz
510(k) history	14 submissions · 14 cleared · 2016-2026

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