

K161588 Vscan ExtendAug 31, 2016
84 days to decisionK161588 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k161588/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jun 8, 2016
Decision date	Aug 31, 2016
Days to decision	84 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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