

**K002397 M2430 DIAGNOSTIC ULTRASOUND SYSTEM WITH
THE 21420 TRANSDUCER**Aug 17, 2000
10 days to decisionK002397 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k002397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 7, 2000
Decision date	Aug 17, 2000
Days to decision	10 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Agilent Technologies, Inc.
Location	Pittsburgh, PA, US
Contact	PAUL SMOLENSKI
Website	http://www.agilent.com
510(k) history	30 submissions · 30 cleared · 1985-2017

Agilent Technologies, Inc. is an American global company that provides instruments, software, services, and consumables for laboratories. Headquartered in Santa Clara, California, Agilent was established in 1999 as a spin-off from Hewlett-Packard. The company has received FDA 510(k) clearances from total submissions. Cardiovascular devices represent the dominant focus, accounting for approximately 80% of regulatory submissions. Agilent's FDA 510(k) clearance history spans from 1985 to 2017, establishing a long track record in medical device regulation. Notable cleared dev...

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