

**K915403 DIAGNOSTIC ULTRASOUND SYSTEM**May 3, 1994  
881 days to decisionK915403 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k915403/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 4, 1991
Decision date	May 3, 1994
Days to decision	881 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Hitachi Medical Systems America, Inc.</b>
Location	Twinsburg, OH, US
Contact	JOCHEN ROGERS
510(k) history	100 submissions · 100 cleared · 1991-2017

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