

**K162065 Ultrasound System SONIMAGE HS1**Oct 19, 2016  
85 days to decisionK162065 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k162065/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 26, 2016
Decision date	Oct 19, 2016
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Konica Minolta, Inc.</b>
Location	New York, NY, US
Contact	Tsutomu Fukui
Website	<a href="http://www.konicaminolta.com">http://www.konicaminolta.com</a>
510(k) history	25 submissions · 25 cleared · 2014-2025

Konica Minolta, Inc. is a global imaging and technology company with a manufacturing facility in New York, US. The company develops advanced diagnostic and imaging solutions for healthcare and industrial applications. Konica Minolta has received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company specializes exclusively in Radiology devices, establishing a focused regulatory portfolio. Its FDA 510(k) clearance history spans from 2014 to 2025, with recent clearances demonstrating continued active development and market engagement...

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