

**K182153 Ultrasound System SONIMAGE HS1**Sep 6, 2018  
29 days to decisionK182153 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k182153/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Aug 8, 2018
Decision date	Sep 6, 2018
Days to decision	29 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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...

---