

K063518 HI VISION 900 DIAGNOSTIC ULTRASOUND SCANNERDec 21, 2006
30 days to decisionK063518 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k063518/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 21, 2006
Decision date	Dec 21, 2006
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hitachi Medical Systems America, Inc.
Location	Twinsburg, OH, US
Contact	DOUG THISTLETHWAITE
510(k) history	100 submissions · 100 cleared · 1991-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k063518/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026