

**K980860 HDI 1000 DIAGNOSTIC ULTRASOUND SYSTEM**Apr 2, 1998  
28 days to decisionK980860 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k980860/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Mar 5, 1998
Decision date	Apr 2, 1998
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Atlantis Diagnostics Intl., Inc.</b>
Location	Bothell, WA, US
Contact	TERRENCE J SWEENEY
510(k) history	3 submissions · 3 cleared · 1995-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k980860/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 19, 2026