

**K043078 NEMIO DIAGNOSTIC ULTRASOUND SYSTEM, MODEL  
SSA-550A**Nov 17, 2004  
9 days to decisionK043078 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k043078/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Nov 8, 2004
Decision date	Nov 17, 2004
Days to decision	9 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Toshiba America Medical Systems, In.C</b>
Location	Tustin, CA, US
Contact	PAUL BIGGINS
510(k) history	146 submissions · 146 cleared · 1989-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043078/>; 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 16, 2026