

**K122574 DIGITAL ULTRASONIC DIAGNOSTIC IMAGING SYSTEM, MODEL D3 AND D6**Oct 12, 2012  
50 days to decisionK122574 · Product code: IYO · Radiology  
Source: <https://www.510kdatabase.net/k122574/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Aug 23, 2012
Decision date	Oct 12, 2012
Days to decision	50 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Edan Instruments, Inc.</b>
Location	Shenzhen, CN
Contact	RANDY JIANG
Website	<a href="https://www.edan.com.cn">https://www.edan.com.cn</a>
510(k) history	92 submissions · 92 cleared · 2004-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122574/> 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 17, 2026