

**K052355 AUTOMATED BREAST ULTRASOUND SYSTEM,  
MODEL ABUS**Sep 14, 2005  
16 days to decisionK052355 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k052355/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Aug 29, 2005
Decision date	Sep 14, 2005
Days to decision	16 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>U-Systems, Inc.</b>
Location	Los Altos,, CA, US
Contact	ROBERT F LAWRENCE
510(k) history	6 submissions · 6 cleared · 2001-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k052355/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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