

**K080555 SOFIA AUTOMATED TOMOGRAPHIC ULTRASOUND  
(ATUS)**Jun 3, 2008  
96 days to decisionK080555 · Product code: **ITX** · Radiology  
Source: <https://www.510kdatabase.net/k080555/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Feb 28, 2008
Decision date	Jun 3, 2008
Days to decision	96 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ivu Imaging Corporation</b>
Location	Grapevine, TX, US
Contact	MARK L STRIBLING
510(k) history	1 submissions · 1 cleared · 2008-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080555/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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