

**K043455 SA8000 SE DIAGNOSTIC ULTRASOUND SYSTEM**Dec 21, 2004  
6 days to decisionK043455 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k043455/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 15, 2004
Decision date	Dec 21, 2004
Days to decision	6 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medison Co., Ltd.</b>
Location	Media, PA, US
Contact	CARL ALLETTO
Website	<a href="http://www.medison.com/">http://www.medison.com/</a>
510(k) history	24 submissions · 24 cleared · 1990-2011

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043455/> 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