

**K121243 ULTRASONIC BIOMETER FOR OPHTHALMOLOGY  
ULTRASONIC PACHYMETER**May 3, 2013  
373 days to decisionK121243 · Product code: IYO · Radiology  
Source: <https://www.510kdatabase.net/k121243/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Apr 25, 2012
Decision date	May 3, 2013
Days to decision	373 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>MEDA Co., Ltd.</b>
Location	Potomac, MD, US
Contact	KAI CHEN
510(k) history	5 submissions · 5 cleared · 2012-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121243/> 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 26, 2026