

K131830 DIGITAL ULTRASONIC DIAGNOSTIC IMAGING SYSTEMSep 17, 2013
89 days to decisionK131830 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k131830/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Jun 20, 2013
Decision date	Sep 17, 2013
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Edan Instruments, Inc.
Location	Shenzhen, CN
Contact	CHERRY SUN
Website	https://www.edan.com.cn
510(k) history	92 submissions · 92 cleared · 2004-2026

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