

**K063433 ULTRASONIC BIOMETER/PACHYETER FOR
OPHTHALMOLOGY ODM 2100 AND ODM 2200**

Jan 29, 2007
77 days to decision

K063433 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k063433/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Nov 13, 2006
Decision date	Jan 29, 2007
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Meda , Ltd.
Location	Cleveland, OH, US
Contact	EDWARD A KROLL
510(k) history	2 submissions · 2 cleared · 2007-2007

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k063433/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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