

K083377 ACCUPENJul 27, 2009
255 days to decisionK083377 · Product code: **HKX** · Ophthalmic
Source: <https://www.510kdatabase.net/k083377/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tonometer, Ac-powered (HKX)
Date received	Nov 14, 2008
Decision date	Jul 27, 2009
Days to decision	255 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Accutome Ultrasound, Inc.
Location	Malvern, PA, US
Contact	BRIAN T.S. BARRETT
510(k) history	3 submissions · 3 cleared · 2004-2009

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