

K123821 AIO HD OTOSCOPEMay 17, 2013
156 days to decisionK123821 · Product code: **ERA** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k123821/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Otoscope (ERA)
Date received	Dec 12, 2012
Decision date	May 17, 2013
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Blue Focus
Location	Lawrenceville, GA, US
Contact	KI CHEOL HAN
510(k) history	1 submissions · 1 cleared · 2013-2013

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