

K101034 NIOX MINO MODEL 09-1000Sep 2, 2010
141 days to decisionK101034 · Product code: **MXA** · Chemistry
Source: <https://www.510kdatabase.net/k101034/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Breath Nitric Oxide (MXA)
Date received	Apr 14, 2010
Decision date	Sep 2, 2010
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aerocrine AB
Location	San Diego, CA, US
Contact	JOHANNA KARLING
510(k) history	6 submissions · 5 cleared · 2003-2015

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