

K213611 Fenom ProJun 7, 2023
569 days to decisionK213611 · Product code: **MXA** · Chemistry
Source: <https://www.510kdatabase.net/k213611/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Breath Nitric Oxide (MXA)
Date received	Nov 15, 2021
Decision date	Jun 7, 2023
Days to decision	569 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Caire Diagnostics, Inc.
Location	Pleasanton, CA, US
Contact	Ryan Leard
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213611/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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