FDA 510(k) Premarket Notification

K251674 Fenom Flo™ FeNO Monitoring System

CLEARED

Nov 26, 2025
180 days to decision

K251674 · Product code: **MXA** · Chemistry
Source: https://www.510kdatabase.net/k251674/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Breath Nitric Oxide (MXA)
Date received	May 30, 2025
Decision date	Nov 26, 2025
Days to decision	180 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mgc Diagnostics Corporation**
Location	St. Paul, MN, US
Contact	Arathi Sundaresan
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Pathmaker FDA Law, PLLC**
Contact	Amy Fowler

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov