

**K203695 NObreath®**Dec 17, 2021  
364 days to decisionK203695 · Product code: **MXA** · Chemistry  
Source: <https://www.510kdatabase.net/k203695/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Breath Nitric Oxide (MXA)
Date received	Dec 18, 2020
Decision date	Dec 17, 2021
Days to decision	364 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Bedfont Scientific, Ltd.</b>
Location	Upchurch, Kent, GB
Contact	Louise Bateman
510(k) history	6 submissions · 6 cleared · 2000-2021

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Bedfont Scientific, LLC C/O Promedic, LLC</b>
Contact	Paul Dryden

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203695/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 24, 2026