FDA 510(k) Premarket Notification

K203695 NObreath®

CLEARED

Dec 17, 2021
364 days to decision

K203695 · 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	**Bedfont Scientific, Ltd.**
Location	Upchurch, Kent, GB
Contact	Louise Bateman
510(k) history	6 submissions · 6 cleared · 2000-2021

REGULATORY CONSULTANT

Consulting firm	**Bedfont Scientific, LLC C/O Promedic, LLC**
Contact	Paul Dryden

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