

K211918 iCOquit® Smokerlyzer®Dec 21, 2021
183 days to decisionK211918 · Product code: **CCJ** · Toxicology
Source: <https://www.510kdatabase.net/k211918/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Carbon-monoxide, Gaseous-phase (CCJ)
Date received	Jun 21, 2021
Decision date	Dec 21, 2021
Days to decision	183 days
Third-party review	Yes
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	Regulatory Technology Services, LLC
Contact	Prithul Bom

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211918/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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