

K193610 BreathID Smart SystemFeb 6, 2020
42 days to decisionK193610 · Product code: **MSQ** · Microbiology
Source: <https://www.510kdatabase.net/k193610/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Test, Urea (breath Or Blood) (MSQ)
Date received	Dec 26, 2019
Decision date	Feb 6, 2020
Days to decision	42 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Exalenz Bioscience , Ltd.
Location	Wheat Ridge, CO, US
Contact	Raffi Werner
510(k) history	5 submissions · 5 cleared · 2013-2020

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