

K162150 BreathID Hp Lab SystemOct 31, 2016
90 days to decisionK162150 · Product code: **MSQ** · Microbiology
Source: <https://www.510kdatabase.net/k162150/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Urea (breath Or Blood) (MSQ)
Date received	Aug 2, 2016
Decision date	Oct 31, 2016
Days to decision	90 days
Third-party review	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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