

K221896 BreathID Hp SystemDec 19, 2022
172 days to decisionK221896 · Product code: **MSQ** · Microbiology
Source: <https://www.510kdatabase.net/k221896/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Test, Urea (breath Or Blood) (MSQ)
Date received	Jun 30, 2022
Decision date	Dec 19, 2022
Days to decision	172 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Meridian Bioscience Israel , Ltd.
Location	Modiin, IL
Contact	Raffi Werner
510(k) history	3 submissions · 3 cleared · 2022-2022

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Device record: <https://www.510kdatabase.net/k221896/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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