

K223185 BreathID® Smart SystemNov 10, 2022
29 days to decisionK223185 · Product code: **MSQ** · Microbiology
Source: <https://www.510kdatabase.net/k223185/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Test, Urea (breath Or Blood) (MSQ)
Date received	Oct 12, 2022
Decision date	Nov 10, 2022
Days to decision	29 days
Third-party review	No
Combination product	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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223185/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026