

**K173777 BreathID Hp Lab System**Mar 8, 2018  
86 days to decisionK173777 · Product code: **MSQ** · Microbiology  
Source: <https://www.510kdatabase.net/k173777/>**SUBMISSION DETAILS**

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Test, Urea (breath Or Blood) (MSQ) |
| Date received         | Dec 12, 2017                       |
| Decision date         | Mar 8, 2018                        |
| Days to decision      | 86 days                            |
| Third-party review    | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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

**REGULATORY CONSULTANT**

|                 |                       |
|-----------------|-----------------------|
| Consulting firm | <b>Medicsense USA</b> |
| Contact         | George Hattub         |

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

**CLINICAL EVIDENCE - NCT02905825****Urea Breath Test (UBT) With Breath Hp System /BreathID Hp Lab System Pediatrics**

|                   |                                      |
|-------------------|--------------------------------------|
| Status            | Completed                            |
| Enrollment        | 54 patients (actual)                 |
| Study sites       | 6 sites                              |
| Condition studied | Helicobacter Pylori Infection        |
| Primary purpose   | Diagnostic                           |
| Study type        | Interventional                       |
| Study design      | Single group                         |
| Masking           | Open label                           |
| Completion date   | Nov 5, 2017                          |
| Sponsor           | Meridian Bioscience, Inc. (Industry) |

**Primary outcome**

Number of Participants With Reported Adverse Events

**Secondary outcome**

Percentage of Agreement

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT02905825](https://clinicaltrials.gov/study/NCT02905825)