FDA 510(k) Premarket Notification

K173772 BreathID Hp System

CLEARED

Mar 8, 2018
86 days to decision

K173772 · Product code: **MSQ** · Microbiology
Source: https://www.510kdatabase.net/k173772/

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

REGULATORY CONSULTANT

Consulting firm	**Medicsense USA**
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