

K183573 Vstrip H. pylori Antigen Rapid Test

Mar 14, 2019
83 days to decision

K183573 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k183573/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Dec 21, 2018
Decision date	Mar 14, 2019
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Panion & BF Biotech, Inc.
Location	New Taipei City, TW
Contact	Ching Sui A. Yi
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Amarex Clinical Research, LLC
Contact	Kazem Kazempour

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