

K181464 LIAISON Helicobacter Antigen, LIAISON Helicobacter Antigen Control SetAug 31, 2018
88 days to decisionK181464 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k181464/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Jun 4, 2018
Decision date	Aug 31, 2018
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	DiaSorin, Inc.
Location	Ellicott City, MD, US
Contact	John C. Walter
510(k) history	70 submissions · 69 cleared · 1998-2025

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