

K151935 Alere Signify H. pylori Whole Blood, Serum, Plasma

Aug 12, 2015
29 days to decision

K151935 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k151935/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Helicobacter Pylori (LYR)
Date received	Jul 14, 2015
Decision date	Aug 12, 2015
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary
Other names	Alere Signify H. pylori Whole Blood Only; Alere Clearview H. pylori Whole Blood, Serum, Plasma; Alere Clearview H. pylori Whole Blood Only

APPLICANT

Company	Alere San Diego, Incorporated
Location	San Deigo, CA, US
Contact	JOSEPH DE LA ROSA
510(k) history	1 submissions · 1 cleared · 2015-2015

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k151935/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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