

K160650 LIAISON HAV IgM, LIAISON Control HAV IgMAug 25, 2016
170 days to decisionK160650 · Product code: **LOL** · Microbiology
Source: <https://www.510kdatabase.net/k160650/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hepatitis A Test (antibody And Igm Antibody) (LOL)
Date received	Mar 8, 2016
Decision date	Aug 25, 2016
Days to decision	170 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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