

K161964 ADVIA Centaur HAV IgM AssayOct 13, 2016
87 days to decisionK161964 · Product code: **LOL** · Microbiology
Source: <https://www.510kdatabase.net/k161964/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hepatitis A Test (antibody And Igm Antibody) (LOL)
Date received	Jul 18, 2016
Decision date	Oct 13, 2016
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics, Inc.
Location	New York, NY, US
Contact	Philip Liu
Website	https://www.siemens-healthineers.com
510(k) history	152 submissions · 151 cleared · 2008-2026

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