

K100903 ANTI-HAVOct 5, 2010
187 days to decisionK100903 · Product code: **LOL** · Microbiology
Source: <https://www.510kdatabase.net/k100903/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hepatitis A Test (antibody And Igm Antibody) (LOL)
Date received	Apr 1, 2010
Decision date	Oct 5, 2010
Days to decision	187 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Roche Professional Diagnostics
Location	Indianapolis, IN, US
Contact	KELLY FRENCH
510(k) history	2 submissions · 2 cleared · 2010-2015

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