

**K060770 VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HAV
IGM-REAGENT PACK, CALIBRATOR, AND CONTROLS**Sep 15, 2006
177 days to decisionK060770 · Product code: **LOL** · Microbiology
Source: <https://www.510kdatabase.net/k060770/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hepatitis A Test (antibody And Igm Antibody) (LOL)
Date received	Mar 22, 2006
Decision date	Sep 15, 2006
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho-Clinical Diagnostics, Inc.
Location	Rochester, NY, US
Contact	SARAH PARSONS
510(k) history	106 submissions · 104 cleared · 1997-2025

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