

K063318 MONOLISA ANTI-HAV EIAMay 3, 2007
182 days to decisionK063318 · Product code: **LOL** · Microbiology
Source: <https://www.510kdatabase.net/k063318/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hepatitis A Test (antibody And Igm Antibody) (LOL)
Date received	Nov 2, 2006
Decision date	May 3, 2007
Days to decision	182 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Rad Laboratories
Location	Hauts-De-Seine, FR
Contact	MANUELA KAUL
Website	http://www.bio-rad.com
510(k) history	46 submissions · 45 cleared · 2007-2019

Bio-Rad Laboratories is an American biotechnology firm founded in 1952 in Berkeley, California. The company develops and manufactures specialized products for life science research and clinical diagnostics, with operations worldwide. Bio-Rad has received FDA 510(k) clearances from total submissions between 2007 and 2019. The company's cleared devices span chemistry devices, microbiology, and immunology categories, with notable focus on diagnostic control materials and multiplex immunoassay systems. This regulatory record reflects the company's historical activity in the c...
