

K132031 AFINION LIPID PANEL AND AFINION LIPID PANEL CONTROLMar 21, 2014
246 days to decisionK132031 · Product code: **CHH** · Chemistry
Source: <https://www.510kdatabase.net/k132031/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Esterase--oxidase, Cholesterol (CHH)
Date received	Jul 18, 2013
Decision date	Mar 21, 2014
Days to decision	246 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Axis-Shield Poc AS
Location	San Diego, CA, US
Contact	KARI SKINNEMOEN
510(k) history	4 submissions · 4 cleared · 2005-2014

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