

**K180504 Mission Lipid Panel Monitoring System**Mar 28, 2018  
30 days to decisionK180504 · Product code: **CHH** · Chemistry  
Source: <https://www.510kdatabase.net/k180504/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzymatic Esterase--oxidase, Cholesterol (CHH)
Date received	Feb 26, 2018
Decision date	Mar 28, 2018
Days to decision	30 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>ACON Laboratories, Inc.</b>
Location	San Diego, CA, US
Contact	Qiyi Xie
Website	<a href="http://www.aconlabs.com/">http://www.aconlabs.com/</a>
510(k) history	85 submissions · 85 cleared · 1998-2025

ACON Laboratories, Inc. is a global medical device manufacturer headquartered in San Diego, California. The company develops and manufactures diagnostic and point-of-care testing devices for hospitals, clinical laboratories, physician offices, blood banks, pharmacies, and veterinary clinics. ACON operates in over 130 countries and maintains FDA-registered manufacturing facilities with ISO 13485 certification. ACON has received FDA 510(k) clearances from total submissions since 1998, with no denied submissions. The company specializes in chemistry devices, including blood ...

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