

K183517 Ammonia IIFeb 8, 2019
52 days to decisionK183517 · Product code: **JIF** · Chemistry
Source: <https://www.510kdatabase.net/k183517/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Ammonia (JIF)
Date received	Dec 18, 2018
Decision date	Feb 8, 2019
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Operations (Rdo)
Location	Indianapolis, IN, US
Contact	Noel B. Mencias
510(k) history	14 submissions · 14 cleared · 2014-2020

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