

K171080 ALP IFCC Gen.2May 10, 2017
29 days to decisionK171080 · Product code: **CJE** · Chemistry
Source: <https://www.510kdatabase.net/k171080/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Nitrophenylphosphate, Alkaline Phosphatase Or Isoenzymes (CJE)
Date received	Apr 11, 2017
Decision date	May 10, 2017
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Operations (Rdo)
Location	Indianapolis, IN, US
Contact	Patrick Stimart
510(k) history	14 submissions · 14 cleared · 2014-2020

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