

K160570 Creatine KinaseMay 25, 2016
86 days to decisionK160570 · Product code: **JHS** · Chemistry
Source: <https://www.510kdatabase.net/k160570/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Differential Rate Kinetic Method, Cpk Or Isoenzymes (JHS)
Date received	Feb 29, 2016
Decision date	May 25, 2016
Days to decision	86 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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