

K121558 DIAZYME HSCR POC TEST KITSep 21, 2012
115 days to decisionK121558 · Product code: **DCK** · Chemistry
Source: <https://www.510kdatabase.net/k121558/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C-reactive Protein, Antigen, Antiserum, And Control (DCK)
Date received	May 29, 2012
Decision date	Sep 21, 2012
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diazyme Laboratories
Location	Irvine, CA, US
Contact	Abhijit Datta
510(k) history	41 submissions · 41 cleared · 2003-2018

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