

K123785 DIAZYME MYOGLOBINJun 7, 2013
179 days to decisionK123785 · Product code: **DDR** · Chemistry
Source: <https://www.510kdatabase.net/k123785/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Myoglobin, Antigen, Antiserum, Control (DDR)
Date received	Dec 10, 2012
Decision date	Jun 7, 2013
Days to decision	179 days
Third-party review	No
Summary / Statement	Summary
Other names	ASSAY, CALIBRATOR SET, CONTROL SET

APPLICANT

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

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