

K082488 DIAZYME LP(A) ASSAYJan 13, 2009
138 days to decisionK082488 · Product code: **DFC** · Chemistry
Source: <https://www.510kdatabase.net/k082488/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipoprotein, Low-density, Antigen, Antiserum, Control (DFC)
Date received	Aug 28, 2008
Decision date	Jan 13, 2009
Days to decision	138 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	General Atomics
Location	San Diego, CA, US
Contact	Abhijit Datta
Website	http://www.ga.com
510(k) history	6 submissions · 6 cleared · 2003-2009

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