

**K161646 Diazyme Folate Assay , Diazyme Folate Calibrator Set,
Diazyme Folate Control Set**Nov 4, 2016
142 days to decisionK161646 · Product code: **CGN** · Chemistry
Source: <https://www.510kdatabase.net/k161646/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acid, Folic, Radioimmunoassay (CGN)
Date received	Jun 15, 2016
Decision date	Nov 4, 2016
Days to decision	142 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161646/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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