

K161721 Diazyme Vitamin B12 Assay, Diazyme Vitamin B12 Calibrators Set, Diazyme Vitamin B12 Controls SetSep 20, 2016
90 days to decisionK161721 · Product code: **CDD** · Chemistry
Source: <https://www.510kdatabase.net/k161721/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioassay, Vitamin B12 (CDD)
Date received	Jun 22, 2016
Decision date	Sep 20, 2016
Days to decision	90 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/k161721/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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