

**K112120 DIAZYME D-DIMER ASSAY KIT,CALIBRATOR SETAND  
CONTROL SET**Jan 24, 2013  
549 days to decisionK112120 · Product code: **GHH** · Hematology  
Source: <https://www.510kdatabase.net/k112120/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrin Split Products (GHH)
Date received	Jul 25, 2011
Decision date	Jan 24, 2013
Days to decision	549 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112120/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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