

K143470 Diazyme Fibrinogen Assay, Diazyme Fibrinogen Calibrator Set, Diazyme Fibrinogen Control SetJan 31, 2016
422 days to decisionK143470 · Product code: **GIS** · Hematology
Source: <https://www.510kdatabase.net/k143470/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Fibrinogen (GIS)
Date received	Dec 5, 2014
Decision date	Jan 31, 2016
Days to decision	422 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

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/k143470/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026