

**K153394 Diazyme Human Kappa Free Light Chain Assay,
Diazyme Human Lambda Free Light Chain Assay, Diazyme
Human Kappa/Lambda Free Light Chain Calibrator, Diazyme
Human Kappa/Lambda Free Light Chain Calibrator**Nov 18, 2016
360 days to decisionK153394 · Product code: DFH · Immunology
Source: <https://www.510kdatabase.net/k153394/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kappa, Antigen, Antiserum, Control (DFH)
Date received	Nov 24, 2015
Decision date	Nov 18, 2016
Days to decision	360 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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