

**K181438 Diazyme Human Kappa Free Light Chain Assay**Jun 26, 2018  
25 days to decisionK181438 · Product code: **DFH** · Immunology  
Source: <https://www.510kdatabase.net/k181438/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Kappa, Antigen, Antiserum, Control (DFH)
Date received	Jun 1, 2018
Decision date	Jun 26, 2018
Days to decision	25 days
Third-party review	No
Summary / Statement	Statement
Other names	Diazyme Human Lambda Free Light Chain Assay

**APPLICANT**

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Company	<b>Diazyme Laboratories, Inc.</b>
Location	Poway, CA, US
Contact	Abhijit Datta
Website	<a href="https://www.diazyme.com/">https://www.diazyme.com/</a>
510(k) history	10 submissions · 10 cleared · 2018-2026

Diazyme Laboratories, Inc. develops innovative clinical diagnostic reagents using proprietary enzyme and immunoassay technologies. Founded in 2000, the company specializes in diagnostic tests for cardiovascular disease, cancer, liver disease, renal disease, diabetes, sepsis, inflammatory disease, vitamins, and electrolytes. Diazyme operates a cGMP and ISO 13485 certified manufacturing facility in Poway, California, with additional operations in Europe and Shanghai. The company has received FDA 510(k) clearances from total submissions since 2018. Diazyme's cleared devices ...