FDA 510(k) Premarket Notification

CLEARED

K211648 Diazyme Human Kappa Free Light Chain Assay, Diazyme Human Lambda Free Light Chain Assay

Sep 8, 2022
468 days to decision

K211648 · Product code: **DFH** · Immunology
Source: https://www.510kdatabase.net/k211648/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kappa, Antigen, Antiserum, Control (DFH)
Date received	May 28, 2021
Decision date	Sep 8, 2022
Days to decision	468 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Diazyme Laboratories, Inc.**
Location	Poway, CA, US
Contact	Abhijit Datta
Website	https://www.diazyme.com/
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 ...