FDA 510(k) Premarket Notification

K180074 Diazyme Lipoprotein (a) Assay

CLEARED

Mar 22, 2018
71 days to decision

K180074 · Product code: **DFC** · Chemistry
Source: https://www.510kdatabase.net/k180074/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipoprotein, Low-density, Antigen, Antiserum, Control (DFC)
Date received	Jan 10, 2018
Decision date	Mar 22, 2018
Days to decision	71 days
Third-party review	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 ...