FDA 510(k) Premarket Notification

K062026 VAP-NT CHOLESTEROL TEST

CLEARED

Mar 6, 2007
231 days to decision

K062026 · Product code: **CHH** · Chemistry
Source: https://www.510kdatabase.net/k062026/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Esterase--oxidase, Cholesterol (CHH)
Date received	Jul 18, 2006
Decision date	Mar 6, 2007
Days to decision	231 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Atherotech, Inc.**
Location	Huntington Beach, CA, US
Contact	Rebecca K Pine
510(k) history	1 submissions · 1 cleared · 2007-2007

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k062026/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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