

K130141 S TEST REAGENT CARTRIDGE ALP (ALKALINE PHOSPHATASE)Mar 22, 2013
59 days to decisionK130141 · Product code: **CJE** · Chemistry
Source: <https://www.510kdatabase.net/k130141/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nitrophenylphosphate, Alkaline Phosphatase Or Isoenzymes (CJE)
Date received	Jan 22, 2013
Decision date	Mar 22, 2013
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hitachi Chemical Diagnostics, Inc.
Location	Mountain View, CA, US
Contact	ERIKA B AMMIRATI, RAC, MT (ASCP)
510(k) history	16 submissions · 16 cleared · 2003-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130141/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026