

K151113 ELITech Clinical Systems CALCIUM ARSENAZOJul 22, 2015
86 days to decisionK151113 · Product code: **CJY** · Chemistry
Source: <https://www.510kdatabase.net/k151113/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Azo Dye, Calcium (CJY)
Date received	Apr 27, 2015
Decision date	Jul 22, 2015
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Elitechgroup
Location	Bothell, WA, US
Contact	Valerie Gourdon
510(k) history	17 submissions · 17 cleared · 2011-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151113/> 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 June 18, 2026