

K151552 ELITech Clinical Systems ELICAL 2, ELITech Clinical Systems ELITROL I, ELITech Clinical Systems ELITROL IIJul 8, 2015
29 days to decisionK151552 · Product code: JIX · Chemistry
Source: <https://www.510kdatabase.net/k151552/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Jun 9, 2015
Decision date	Jul 8, 2015
Days to decision	29 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/k151552/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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