

K153644 ELITech Clinical Systems GLUCOSE HK SL, ELITech Clinical Systems ELICAL 2, ELITech Clinical Systems ELITROL I and ELITROL II

Sep 7, 2016
261 days to decision

K153644 · Product code: **CFR** · Chemistry
Source: <https://www.510kdatabase.net/k153644/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hexokinase, Glucose (CFR)
Date received	Dec 21, 2015
Decision date	Sep 7, 2016
Days to decision	261 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.net

Device record: <https://www.510kdatabase.net/k153644/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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