

**K122858 ELTECH CHINICAL SYSTEM AMYLASE SL ELITECH
 CLINICAL SYSTEMS ELICAL2 ELTECH CLINICAL SYSTEMS
 ELITROL I AND ELITROL II**

Oct 3, 2012
 15 days to decision

K122858 · Product code: **JFJ** · Chemistry
 Source: <https://www.510kdatabase.net/k122858/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Sep 18, 2012
Decision date	Oct 3, 2012
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k122858/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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