

**K132399 ELITECH CLINICAL SYSTEMS CREATININE PAP SL, ELICAL 2, ELITROL I AND ELITROL II, URINE CONTROL BI-LEVEL**

Jan 3, 2014  
155 days to decision

K132399 · Product code: **JFY** · Chemistry  
Source: <https://www.510kdatabase.net/k132399/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	Aug 1, 2013
Decision date	Jan 3, 2014
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k132399/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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