

**K141265 ELITECH CLINICAL SYSTEMS ENVOY 500 CK  
REAGENT KIT**Jul 18, 2014  
64 days to decisionK141265 · Product code: **JHW** · Chemistry  
Source: <https://www.510kdatabase.net/k141265/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	U.v. Method, Cpk Isoenzymes (JHW)
Date received	May 15, 2014
Decision date	Jul 18, 2014
Days to decision	64 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/k141265/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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