

**K061412 THERMO ELECTRON ENZYMATIC CREATININE,  
MODEL TR35401**Mar 23, 2007  
305 days to decisionK061412 · Product code: JFY · Chemistry  
Source: <https://www.510kdatabase.net/k061412/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	May 22, 2006
Decision date	Mar 23, 2007
Days to decision	305 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Thermo-Electron Corp.</b>
Location	Noble Park, AU
Contact	BOLA NICHOLSON
510(k) history	3 submissions · 3 cleared · 2005-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061412/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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