

**K112416 CPK REAGENT**Nov 9, 2011  
79 days to decisionK112416 · Product code: **CGS** · Chemistry  
Source: <https://www.510kdatabase.net/k112416/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Aug 22, 2011
Decision date	Nov 9, 2011
Days to decision	79 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Vital Diagnostics (Manufacturing) Ptyltd</b>
Location	Noble Park, AU
Contact	MELITA LAMBIRIS
510(k) history	5 submissions · 5 cleared · 2010-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112416/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 14, 2026