

**K852392 EDC/TITAN GELISO-TOTAL CPK ISOENZYME  
PROCEDURE**Oct 22, 1985  
139 days to decisionK852392 · Product code: **CGS** · Chemistry  
Source: <https://www.510kdatabase.net/k852392/>**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	Jun 5, 1985
Decision date	Oct 22, 1985
Days to decision	139 days
Third-party review	No

**APPLICANT**

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Company	<b>Helena Laboratories</b>
Location	Mchenry, IL, US
Contact	BARBARA WARREN
510(k) history	280 submissions · 280 cleared · 1978-2013

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k852392/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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