

**K842755 TITAN GEL ISO DOT CPK PROCEDURE**Sep 28, 1984  
74 days to decisionK842755 · Product code: **CGS** · Chemistry  
Source: <https://www.510kdatabase.net/k842755/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Jul 16, 1984
Decision date	Sep 28, 1984
Days to decision	74 days
Third-party review	No

**APPLICANT**

---

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

---

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

Device record: <https://www.510kdatabase.net/k842755/> 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 May 14, 2026