

**K120900 I-STAT PT CONTROL LEVEL 1 I-STAT PT CONTROL  
LEVEL 2**May 31, 2013  
431 days to decisionK120900 · Product code: **GGN** · Hematology  
Source: <https://www.510kdatabase.net/k120900/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Mar 26, 2012
Decision date	May 31, 2013
Days to decision	431 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Cliniqa Corporation</b>
Location	Fallbrook, CA, US
Contact	DAWN GAST
510(k) history	36 submissions · 36 cleared · 2001-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120900/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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