

**K101947 IVD-GE02**Mar 16, 2011  
247 days to decisionK101947 · Product code: **CGA** · Chemistry  
Source: <https://www.510kdatabase.net/k101947/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Jul 12, 2010
Decision date	Mar 16, 2011
Days to decision	247 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sphere Medical , Ltd.</b>
Location	Cambridge, GB
Contact	MARY HUTCHENS
510(k) history	1 submissions · 1 cleared · 2011-2011

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