

**K113636 BLOOD GLUCOSE MONITORING SYSTEM (GLUCOSE OXIDASE)**

Mar 8, 2013  
455 days to decision

K113636 · Product code: **CGA** · Chemistry  
Source: <https://www.510kdatabase.net/k113636/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Dec 9, 2011
Decision date	Mar 8, 2013
Days to decision	455 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Philosys Co., Ltd.</b>
Location	New York, NY, US
Contact	LINDA CHAN
510(k) history	1 submissions · 1 cleared · 2013-2013

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

Device record: <https://www.510kdatabase.net/k113636/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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