

**K103116 AP-2000, AP-2010, AND AP-2020 BLOOD GLUCOSE MONITORING SYSTEM**

Mar 13, 2012  
509 days to decision

K103116 · Product code: **CGA** · Chemistry  
Source: <https://www.510kdatabase.net/k103116/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Oct 21, 2010
Decision date	Mar 13, 2012
Days to decision	509 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bestgen Biotech Corp.</b>
Location	Hsin Chu City, TW
Contact	STEVEN SHEN
510(k) history	6 submissions · 6 cleared · 2008-2012

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

Device record: <https://www.510kdatabase.net/k103116/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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