

K113670 ELEMENT BLOOD GLUCOSE MONITORING SYSTEMMay 8, 2012
147 days to decisionK113670 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k113670/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Dec 13, 2011
Decision date	May 8, 2012
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Infopia Co, Ltd.
Location	Anyang Kvunggi, KR
Contact	Priscilla Chung
510(k) history	20 submissions · 20 cleared · 2005-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113670/> Data sourced from FDA 510(k) public records (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. - Generated June 2, 2026