

K102316 GLUCOSE SHEPHERD BLOOD GLUCOSE MONITORING SYSTEMOct 7, 2011
417 days to decisionK102316 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k102316/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Aug 16, 2010
Decision date	Oct 7, 2011
Days to decision	417 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Broadmaster Biotech Corporation
Location	Zhonghe City, TW
Contact	ROGER LAI
510(k) history	2 submissions · 2 cleared · 2011-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k102316/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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