FDA 510(k) Premarket Notification

K061431 EASYGLUCO, MODEL IGM-0002 G2

CLEARED

Jan 12, 2007
233 days to decision

K061431 · Product code: **CGA** · Chemistry
Source: https://www.510kdatabase.net/k061431/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	May 24, 2006
Decision date	Jan 12, 2007
Days to decision	233 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**U. S. Diagnostics, Inc.**
Location	San Luis Obispo, CA, US
Contact	EDWARD LETKO
510(k) history	22 submissions · 22 cleared · 1986-2011

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k061431/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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