FDA 510(k) Premarket Notification

K051651 G4, MODEL IGM-0004

CLEARED

Apr 14, 2006
297 days to decision

K051651 · Product code: **NBW** · Chemistry
Source: https://www.510kdatabase.net/k051651/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Jun 21, 2005
Decision date	Apr 14, 2006
Days to decision	297 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/k051651/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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