

K922136 ULTRA+ BLOOD GLUCOSE MONITORING TEST STRIPAug 10, 1993
475 days to decisionK922136 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k922136/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Apr 22, 1992
Decision date	Aug 10, 1993
Days to decision	475 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Home Diagnostics, Inc.
Location	Eatontown, NJ, US
Contact	Maureen Garner
510(k) history	22 submissions · 22 cleared · 1985-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k922136/> 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 23, 2026