

**K010403 PRESTIGE IQ BLOOD GLUCOSE TEST SYSTEM,
MODEL 507400, 537600, 550600, 561700, 563700**Mar 26, 2001
42 days to decisionK010403 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k010403/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Feb 12, 2001
Decision date	Mar 26, 2001
Days to decision	42 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010403/> 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