

K011479 ONE TOUCH FASTTAKE COMPACT BLOOD GLUCOSE MONITORING SYSTEM, ONE TOUCH ULTRA BLOOD GLUCOSE MONITORING SYSTEMNov 30, 2001
200 days to decisionK011479 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k011479/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	May 14, 2001
Decision date	Nov 30, 2001
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Inverness Medical Innovations, Inc.
Location	Waltham, MA, US
Contact	CAROL A ADILETTO
510(k) history	6 submissions · 6 cleared · 2001-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011479/>; 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 26, 2026