

**K043197 ONETOUCH ULTRA, INDUO AND ULTRASMART
BLOOD GLUCOSE MONITORING SYSTEM**May 20, 2005
183 days to decisionK043197 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k043197/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Nov 18, 2004
Decision date	May 20, 2005
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lifescan, Inc.
Location	Mchenry, IL, US
Contact	MARY ELLEN HOLDEN
510(k) history	42 submissions · 42 cleared · 1981-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k043197/>; 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 7, 2026