

**K983504 PRECISION XTRA ADVANCED DIABETES
MANAGEMENT SYSTEM, PRECISION BLOOD GLUCOSE TEST
STRIPS, PRECISION XTRA B-KETONE TEST ST**Jul 9, 1999
276 days to decisionK983504 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k983504/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Oct 6, 1998
Decision date	Jul 9, 1999
Days to decision	276 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medisense, Inc.
Location	Cambridge, MA, US
Contact	MICHAEL HALPIN
510(k) history	15 submissions · 15 cleared · 1990-1999

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