

K901613 MEDISENSE PEN 2/COMPANION 2 BLOOD GLUCOSE SYSTEMJul 10, 1990
95 days to decisionK901613 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k901613/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Apr 6, 1990
Decision date	Jul 10, 1990
Days to decision	95 days
Third-party review	No

APPLICANT

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

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