

**K001427 MODIFICATION TO FASTTAKE COMPACT BLOOD
GLUCOSE MONITORING SYSTEM**Jun 2, 2000
28 days to decisionK001427 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k001427/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	May 5, 2000
Decision date	Jun 2, 2000
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Selfcare, Inc.
Location	Waltham, MA, US
Contact	CAROL A ADILETTO
510(k) history	15 submissions · 15 cleared · 1996-2000

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