

K894483 GLUCOSE-HK TEST (GLU-HK) ITEM #65415Sep 7, 1989
51 days to decisionK894483 · Product code: **CFR** · Chemistry
Source: <https://www.510kdatabase.net/k894483/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hexokinase, Glucose (CFR)
Date received	Jul 18, 1989
Decision date	Sep 7, 1989
Days to decision	51 days
Third-party review	No

APPLICANT

Company	Em Diagnostic Systems, Inc.
Location	Walker, MI, US
Contact	ANNA G BENTLEY
510(k) history	288 submissions · 288 cleared · 1984-1994

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