

K131727 CERA-CHEK 1070 BLOOD GLUCOSE MONITORING SYSTEMFeb 28, 2014
261 days to decisionK131727 · Product code: LFR · Chemistry
Source: <https://www.510kdatabase.net/k131727/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Dehydrogenase, Glucose (LFR)
Date received	Jun 12, 2013
Decision date	Feb 28, 2014
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ceragem Medisys, Inc.
Location	Los Angeles, CA, US
Contact	HAKSUNG KIM
510(k) history	4 submissions · 4 cleared · 2013-2014

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