

**K120369 HITACHI CLINICAL ANALYZER S TEST REAGENT
CARTRIDGE GLUCOSE (GLU)**May 10, 2012
94 days to decisionK120369 · Product code: CFR · Chemistry
Source: <https://www.510kdatabase.net/k120369/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hexokinase, Glucose (CFR)
Date received	Feb 6, 2012
Decision date	May 10, 2012
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hitachi Chemical Diagnostics, Inc.
Location	Mountain View, CA, US
Contact	BUNICHIRO NAKAJIMA
510(k) history	16 submissions · 16 cleared · 2003-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120369/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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