

K131217 S TEST REAGENT CARTRIDGE TOTAL BILIRUBINJun 7, 2013
38 days to decisionK131217 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k131217/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Apr 30, 2013
Decision date	Jun 7, 2013
Days to decision	38 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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