

K130685 HITACHI CLINICAL ANALYZER S TEST REAGENT CARTRIDGES FOR LD AND AMY

Aug 9, 2013
149 days to decision

K130685 · Product code: JFJ · Chemistry
Source: <https://www.510kdatabase.net/k130685/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Mar 13, 2013
Decision date	Aug 9, 2013
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k130685/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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