

**K030590 CLA ALLERGEN-SPECIFIC IGE ASSAY-LATEX
ALLERGEN (K82)**Mar 21, 2003
24 days to decisionK030590 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k030590/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Feb 25, 2003
Decision date	Mar 21, 2003
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k030590/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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