

K051677 OPTIGEN ALLERGEN SPECIFIC IGE ASSAYJan 23, 2006
216 days to decisionK051677 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k051677/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Jun 21, 2005
Decision date	Jan 23, 2006
Days to decision	216 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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