

K945748 HYCOR SPECIFIC IGE ENZYME IMMUNOASSAYJun 7, 1995
196 days to decisionK945748 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k945748/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Nov 23, 1994
Decision date	Jun 7, 1995
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hycor Biomedical, Inc.
Location	Garden Grove, CA, US
Contact	JIM TUNG
510(k) history	51 submissions · 51 cleared · 1989-2008

Hycor Biomedical, Inc. is an American manufacturer of in vitro diagnostic products for blood testing. The company is based in Garden Grove, California and specializes in allergy and autoimmune testing solutions. Hycor Biomedical has received FDA 510(k) clearances from total submissions since its first clearance in 1989. The company's regulatory portfolio is dominated by Immunology devices, which represent the majority of its cleared submissions. The latest FDA 510(k) clearance on record dates to 2008, reflecting the company's historical significance in the diagnostic devi...

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