FDA 510(k) Premarket Notification

K941057 SPECIFIC IGE EIA-ULTRA ASSAY

CLEARED

Jan 20, 1995
318 days to decision

K941057 · Product code: **DHB** · Immunology
Source: https://www.510kdatabase.net/k941057/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Mar 8, 1994
Decision date	Jan 20, 1995
Days to decision	318 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hycor Biomedical, Inc.**
Location	Garden Grove, CA, US
Contact	THOMAS J FOLEY, PH.D
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...