FDA 510(k) Premarket Notification

K081217 HY-TEC SPECIFIC AND TOTAL IGE EIA SYSTEM

CLEARED

May 22, 2008
22 days to decision

K081217 · Product code: **DHB** · Immunology
Source: https://www.510kdatabase.net/k081217/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Apr 30, 2008
Decision date	May 22, 2008
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hycor Biomedical, Inc.**
Location	Garden Grove, CA, US
Contact	P. NARAYAN NAYAK
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...