FDA 510(k) Premarket Notification

K962730 HYCOR HY.TEC/MANUAL DS-DNA AUTO-ANTIBODY

CLEARED

Mar 7, 1997
249 days to decision

K962730 · Product code: **LRM** · Immunology
Source: https://www.510kdatabase.net/k962730/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-dna Antibody (enzyme-labeled), Antigen, Control (LRM)
Date received	Jul 1, 1996
Decision date	Mar 7, 1997
Days to decision	249 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Hycor Biomedical, Inc.**
Location	Garden Grove, CA, US
Contact	MEHDI ALEM, 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...