FDA 510(k) Premarket Notification

K901334 HYCOR ACCUPINCH THC TEST

CLEARED

May 14, 1990
53 days to decision

K901334 · Product code: **LDJ** · Toxicology
Source: https://www.510kdatabase.net/k901334/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cannabinoids (LDJ)
Date received	Mar 22, 1990
Decision date	May 14, 1990
Days to decision	53 days
Third-party review	No

APPLICANT

Company	**Hycor Biomedical, Inc.**
Location	Garden Grove, CA, US
Contact	RON HOOVER
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...