FDA 510(k) Premarket Notification

K896937 HYCOR ACCUPINCH COCAINE TEST

CLEARED

Mar 6, 1990
83 days to decision

K896937 · Product code: **DIO** · Toxicology
Source: https://www.510kdatabase.net/k896937/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Dec 13, 1989
Decision date	Mar 6, 1990
Days to decision	83 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...