

K892332 DRUGS OF ABUSE URINE CALIBRATORSMay 11, 1989
36 days to decisionK892332 · Product code: **DKB** · Toxicology
Source: <https://www.510kdatabase.net/k892332/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Mixture (DKB)
Date received	Apr 5, 1989
Decision date	May 11, 1989
Days to decision	36 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...
