K852320 COBAS FP REAGEN FOR PROCAINAMIDE & PRO CALIBRATOR

CLEARED

Jul 9, 1985
39 days to decision

K852320 · Product code: **LAR** · Toxicology
Source: https://www.510kdatabase.net/k852320/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Procainamide (LAR)
Date received	May 31, 1985
Decision date	Jul 9, 1985
Days to decision	39 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	**Roche Diagnostic Systems, Inc.**
Location	Mchenry, IL, US
Contact	DONALD KAFADER
510(k) history	296 submissions · 296 cleared · 1983-1999