

**K993360 PRECINORM UNIVERSAL PLUS AND PRECIPATH
UNIVERSAL PLUS CONTROL SERA**Nov 24, 1999
49 days to decisionK993360 · Product code: JJY · Immunology
Source: <https://www.510kdatabase.net/k993360/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Oct 6, 1999
Decision date	Nov 24, 1999
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	PRISCILLA A HAMILL
510(k) history	264 submissions · 263 cleared · 1999-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k993360/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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