

K935075 SPQ CRP CONTROL LEVEL IIJan 11, 1994
78 days to decisionK935075 · Product code: **DCN** · Immunology
Source: <https://www.510kdatabase.net/k935075/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, C-reactive Protein (DCN)
Date received	Oct 25, 1993
Decision date	Jan 11, 1994
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Incstar Corp.
Location	Stillwater, MN, US
Contact	MARY E BEST
510(k) history	58 submissions · 57 cleared · 1987-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k935075/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026