

**K050119 PARAGON CZE 2000 URINE PROTEIN
ELECTROPHORESIS KIT AND URINE IMMUNOFIXATION BY
SUBTRACTION KIT**May 6, 2005
108 days to decisionK050119 · Product code: **JKM** · Immunology
Source: <https://www.510kdatabase.net/k050119/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunochemical, Bence-jones Protein (JKM)
Date received	Jan 18, 2005
Decision date	May 6, 2005
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Beckman Coulter, Inc.
Location	Chaska, MN, US
Contact	KIM WALKER
Website	https://www.beckmancoulter.com
510(k) history	270 submissions · 270 cleared · 1993-2026

Beckman Coulter, Inc. is a diagnostic device manufacturer headquartered in Chaska, US. The company specializes in clinical laboratory and immunodiagnostic systems. Beckman Coulter has received FDA 510(k) clearances from total submissions since its first clearance in 1993. The company maintains active regulatory status, with the latest clearance in 2026. Its portfolio spans chemistry devices, microbiology testing systems, hematology analyzers, and immunoassay platforms. Recent cleared devices include chemistry assays for cardiac markers, microbiology susceptibility panels,...