

**K002799 PARAGON CZE 2000 CAPILLARY  
ELECTROPHORESIS SYSTEM AND BUFFER-100**Oct 5, 2000  
27 days to decisionK002799 · Product code: **CFF** · Chemistry  
Source: <https://www.510kdatabase.net/k002799/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Immunoelectrophoretic, Immunoglobulins, (g, A, M) (CFF)
Date received	Sep 8, 2000
Decision date	Oct 5, 2000
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beckman Coulter, Inc.</b>
Location	Chaska, MN, US
Contact	ANNETTE HELLIE
Website	<a href="https://www.beckmancoulter.com">https://www.beckmancoulter.com</a>
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,...