

**K060130 IMAGE SYSTEMS LOW CONCENTRATION  
IMMUNOGLOBULIN A REAGENT**Feb 13, 2006  
26 days to decisionK060130 · Product code: **CZP** · Immunology  
Source: <https://www.510kdatabase.net/k060130/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Iga, Antigen, Antiserum, Control (CZP)
Date received	Jan 18, 2006
Decision date	Feb 13, 2006
Days to decision	26 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,...