

**K963868 IMAGE IMMUNOCHEMISTRY SYSTEM
IMMUNOGLOBULIN G (IGG), A (IGA) AND M (IGM)**Feb 10, 1997
137 days to decisionK963868 · Product code: **DEW** · Immunology
Source: <https://www.510kdatabase.net/k963868/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Igg, Antigen, Antiserum, Control (DEW)
Date received	Sep 26, 1996
Decision date	Feb 10, 1997
Days to decision	137 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beckman Instruments, Inc.
Location	Mchenry, IL, US
Contact	ANNETTE HELLIE
Website	https://www.beckman.com
510(k) history	281 submissions · 281 cleared · 1976-1998

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