

K981912 HUMAN IGA SUBCLASS BNII COMBI KITDec 4, 1998
186 days to decisionK981912 · Product code: **CFN** · Immunology
Source: <https://www.510kdatabase.net/k981912/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Jun 1, 1998
Decision date	Dec 4, 1998
Days to decision	186 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	The Binding Site, Ltd.
Location	Los Angeles, CA, US
Contact	JAY H GELLER
510(k) history	115 submissions · 115 cleared · 1988-2024

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