

**K982100 IGG AND IGG SUBCLASS NEPHELOMETRIC
DIAGNOSTIC TEST KITS**

Dec 20, 1999
553 days to decision

K982100 · Product code: **CFN** · Immunology
Source: <https://www.510kdatabase.net/k982100/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Jun 15, 1998
Decision date	Dec 20, 1999
Days to decision	553 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k982100/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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