

**K981915 TURBIDIMETRIC/NEPHELOMETRIC HUMAN
COMPLEMENT REFERENCE PREPARATION**

Dec 20, 1999
567 days to decision

K981915 · Product code: JJY · Immunology
Source: <https://www.510kdatabase.net/k981915/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Jun 1, 1998
Decision date	Dec 20, 1999
Days to decision	567 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/k981915/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026