

**K012296 HUMAN IGG SUBCLASS LIQUID REAGENT KITS,
PRODUCT CODE LK001.T**Aug 31, 2001
42 days to decisionK012296 · Product code: **CFN** · Immunology
Source: <https://www.510kdatabase.net/k012296/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Jul 20, 2001
Decision date	Aug 31, 2001
Days to decision	42 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.netDevice record: <https://www.510kdatabase.net/k012296/> 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