

K090920 HUMAN IGG SUBCLASS LIQUID REAGENT KITS (FOR USE ON HITACHI 911/ 912/ 917 AND MODULAR P)

Dec 30, 2009
273 days to decision

K090920 · Product code: **CFN** · Immunology
Source: <https://www.510kdatabase.net/k090920/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Apr 1, 2009
Decision date	Dec 30, 2009
Days to decision	273 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/k090920/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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