

**K994112 MANUAL HER-2/NEU MICROTITER ELISA (OSDI
HER-2/NEU ELISA)**Sep 29, 2000
298 days to decisionK994112 · Product code: **NCW** · Immunology
Source: <https://www.510kdatabase.net/k994112/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Her-2/neu, Monitoring (NCW)
Date received	Dec 6, 1999
Decision date	Sep 29, 2000
Days to decision	298 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Oncogene Science, Inc.
Location	Cambridge, MA, US
Contact	WALTER P CARNEY
510(k) history	3 submissions · 3 cleared · 2000-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k994112/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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