

K080384 HUMAN CYSTATIN C KIT FOR USE ON MODULAR P ANALYSERJun 6, 2008
114 days to decisionK080384 · Product code: **NDY** · Chemistry
Source: <https://www.510kdatabase.net/k080384/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Cystatin C (NDY)
Date received	Feb 13, 2008
Decision date	Jun 6, 2008
Days to decision	114 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/k080384/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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