

K113349 HUMAN CH50 REAGENT PACK FOR USE ON THE SPAPLUS, HUMAN CH50 CALIBRATOR SET FOR USE ON THE SPAPLUS, HUMAN CH50 CONTROLS FOJul 11, 2012
240 days to decisionK113349 · Product code: **DAE** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Complement C9, Antigen, Antiserum, Control (DAE)
Date received	Nov 14, 2011
Decision date	Jul 11, 2012
Days to decision	240 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	The Binding Site Group , Ltd.
Location	Los Angeles, CA, US
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510(k) history	43 submissions · 43 cleared · 2010-2025

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