

**K031563 BINDAZYME CLQ CIC EIA KIT**Sep 10, 2003  
114 days to decisionK031563 · Product code: **DAK** · Immunology  
Source: <https://www.510kdatabase.net/k031563/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Complement C1q, Antigen, Antiserum, Control (DAK)
Date received	May 19, 2003
Decision date	Sep 10, 2003
Days to decision	114 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>The Binding Site, Ltd.</b>
Location	Los Angeles, CA, US
Contact	JAY H GELLER
510(k) history	115 submissions · 115 cleared · 1988-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031563/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026