

**K973391 CHEMMATE KAPPA**Oct 3, 1997  
85 days to decisionK973391 · Product code: **DEM** · Immunology  
Source: <https://www.510kdatabase.net/k973391/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alpha-1-antitrypsin, Antigen, Antiserum, Control (DEM)
Date received	Jul 10, 1997
Decision date	Oct 3, 1997
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ventana Medical Systems, Inc.</b>
Location	Tucson, AZ, US
Contact	KATHLEEN WINDALL
Website	<a href="http://www.ventana.com/">http://www.ventana.com/</a>
510(k) history	48 submissions · 46 cleared · 1992-2024

Ventana Medical Systems, Inc. specializes in immunohistochemical staining reagents and antibody-based diagnostic solutions, with a manufacturing facility in Tucson, Arizona. The company develops primary antibodies and prediluted reagents for pathology laboratories and immunology applications. Ventana has received FDA 510(k) clearances from total submissions since 1992, establishing a strong regulatory track record in immunology devices. The company remains active, with its most recent clearance in 2024, demonstrating continued innovation in antibody-based diagnostic produ...

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