

**K941397 ANTI-VIMENTIN PRIMARY ANTIBODY**Feb 10, 1997  
1056 days to decisionK941397 · Product code: **DEH** · Immunology  
Source: <https://www.510kdatabase.net/k941397/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lambda, Antigen, Antiserum, Control (DEH)
Date received	Mar 22, 1994
Decision date	Feb 10, 1997
Days to decision	1056 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	STEPHEN A TILLSON
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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