

**K111543 VIRTUOSO (TM) SYSTEM FOR IHC HER2 (4B5)**Oct 12, 2011  
132 days to decisionK111543 · Product code: **NOT** · Pathology  
Source: <https://www.510kdatabase.net/k111543/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Jun 2, 2011
Decision date	Oct 12, 2011
Days to decision	132 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	INDU LAKSHMAN
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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