

**K111869 VIRTUOSO SYSTEM FOR IHC PR (IE2)**Mar 5, 2012  
248 days to decisionK111869 · Product code: **NQN** · Pathology  
Source: <https://www.510kdatabase.net/k111869/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Microscope, Automated, Image Analysis, Immunohistochemistry,operator Intervention,nuclear Intensity & Percent Positivity (NQN)
Date received	Jul 1, 2011
Decision date	Mar 5, 2012
Days to decision	248 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	TROY QUANDER
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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