

K121033 VIRTUOSO SYSTEM FOR IHC KI-67 (30-9)Sep 6, 2013
519 days to decisionK121033 · Product code: **NOT** · Pathology
Source: <https://www.510kdatabase.net/k121033/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Apr 5, 2012
Decision date	Sep 6, 2013
Days to decision	519 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ventana Medical Systems, Inc.
Location	Tucson, AZ, US
Contact	ERIKA AMMIRATI
Website	http://www.ventana.com/
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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