

K130515 VIRTUOSO SYSTEM FOR IHC ER (SPI)Nov 22, 2013
268 days to decisionK130515 · Product code: **NQN** · Pathology
Source: <https://www.510kdatabase.net/k130515/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Microscope, Automated, Image Analysis, Immunohistochemistry,operator Intervention,nuclear Intensity & Percent Positivity (NQN)
Date received	Feb 27, 2013
Decision date	Nov 22, 2013
Days to decision	268 days
Third-party review	No
Summary / Statement	Statement

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...
