

**K110215 CONFIRM ANTI-ESTROGEN RECEPTOR (SP1) RABBIT
MONOCLONAL PRIMARY ANTIBODY**Dec 17, 2012
719 days to decisionK110215 · Product code: **MYA** · Pathology
Source: <https://www.510kdatabase.net/k110215/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunohistochemistry Antibody Assay, Estrogen Receptor (MYA)
Date received	Dec 29, 2010
Decision date	Dec 17, 2012
Days to decision	719 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ventana Medical Systems, Inc.
Location	Tucson, AZ, US
Contact	ROXANE BONNER
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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Device record: <https://www.510kdatabase.net/k110215/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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