

K990618 VENTANA PGR PRIMARY ANTIBODY (CLONE 1A6)Jul 23, 1999
148 days to decisionK990618 · Product code: **MXZ** · Pathology
Source: <https://www.510kdatabase.net/k990618/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunohistochemistry Assay, Antibody, Progesterone Receptor (MXZ)
Date received	Feb 25, 1999
Decision date	Jul 23, 1999
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ventana Medical Systems, Inc.
Location	Tucson, AZ, US
Contact	JUDITH FREDERICK
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...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k990618/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026