

**K101234 VENTANA ANTI-HELICOBACTER PYLORI (SP48)
RABBIT MONOCLONAL PRIMARY ANTIBODY**Aug 25, 2011
479 days to decisionK101234 · Product code: **OWF** · Microbiology
Source: <https://www.510kdatabase.net/k101234/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunohistochemical Assay, Helicobacter Pylori (OWF)
Date received	May 3, 2010
Decision date	Aug 25, 2011
Days to decision	479 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ventana Medical Systems, Inc.
Location	Tucson, AZ, US
Contact	Judy Howe
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...