

K940243 VENTANA EMA PRIMARY ANDIBODYSep 7, 1994
231 days to decisionK940243 · Product code: **DHF** · Immunology
Source: <https://www.510kdatabase.net/k940243/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	D/km-1, Antigen, Antiserum, Control (DHF)
Date received	Jan 19, 1994
Decision date	Sep 7, 1994
Days to decision	231 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ventana Medical Systems, Inc.
Location	Tucson, AZ, US
Contact	KATHLEEN WINDALL
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...
