FDA 510(k) Premarket Notification

K940331 KERATIN PRIMARY ANTIBODY

CLEARED

Feb 26, 1996
763 days to decision

K940331 · Product code: **DEH** · Immunology
Source: https://www.510kdatabase.net/k940331/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lambda, Antigen, Antiserum, Control (DEH)
Date received	Jan 24, 1994
Decision date	Feb 26, 1996
Days to decision	763 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...