

K212176 CINtec HistologyDec 10, 2021
151 days to decisionK212176 · Product code: **PRB** · Pathology
Source: <https://www.510kdatabase.net/k212176/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cervical Intraepithelial Neoplasia (cin) Test System (PRB)
Date received	Jul 12, 2021
Decision date	Dec 10, 2021
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ventana Medical Systems, Inc.
Location	Tucson, AZ, US
Contact	Stacci Cronk
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...