FDA 510(k) Premarket Notification

CLEARED

K063143 VITROS IMMUNODIAGNOSTIC PRODUCTS RUBELLA IGG REAGANT PACK AND CALIBRATORS

Dec 26, 2006
71 days to decision

K063143 · Product code: **LFX** · Microbiology
Source: https://www.510kdatabase.net/k063143/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Oct 16, 2006
Decision date	Dec 26, 2006
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ortho-Clinical Diagnostics, Inc.**
Location	Rochester, NY, US
Contact	CHARLOTTE BAKER
510(k) history	106 submissions · 104 cleared · 1997-2025