FDA 510(k) Premarket Notification

CLEARED

K221355 VITROS Immuodiagnostic Products CA 125 II Reagent Pack

Dec 12, 2022
216 days to decision

K221355 · Product code: **LTK** · Immunology
Source: https://www.510kdatabase.net/k221355/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Epithelial Ovarian Tumor-associated Antigen (ca125) (LTK)
Date received	May 10, 2022
Decision date	Dec 12, 2022
Days to decision	216 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ortho-Clinical Diagnostics**
Location	Rochester, NY, US
Contact	Rebecca Lewis
510(k) history	38 submissions · 38 cleared · 1999-2024

Ortho-Clinical Diagnostics is an in vitro diagnostics company specializing in clinical laboratory testing and immunohematology. Now part of QuidelOrtho, the brand operates with global research and development centered in Rochester, New York. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions since 1999. Recent clearances span chemistry devices, immunology assays, and microbiology reagents, reflecting the company's focus on diagnostic platforms and assays for disease detection and blood compatibility testing. The V...