

K993068 VITROS IMMUNODIAGNOSTIC PRODUCTS CK-MB REAGENT PACKOct 4, 1999
21 days to decisionK993068 · Product code: JHX · Chemistry
Source: <https://www.510kdatabase.net/k993068/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fluorometric Method, Cpk Or Isoenzymes (JHX)
Date received	Sep 13, 1999
Decision date	Oct 4, 1999
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary
Other names	VITROS IMMUNODIAGNOSTIC PRODUCTS CK-MB CALIBRATORS

APPLICANT

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

Ortho-Clinical Diagnostics is an in vitro diagnostics company specializing in clinical laboratory testing and immuno-hematology. 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...

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Device record: <https://www.510kdatabase.net/k993068/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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