

## K212648 VITROS Immunodiagnostic Products CK-MB Reagent Pack

Jan 28, 2022  
158 days to decision

K212648 · Product code: JHX · Chemistry  
Source: <https://www.510kdatabase.net/k212648/>

### SUBMISSION DETAILS

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorometric Method, Cpk Or Isoenzymes (JHX)
Date received	Aug 23, 2021
Decision date	Jan 28, 2022
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

### APPLICANT

---

Company	<b>Ortho-Clinical Diagnostics</b>
Location	Rochester, NY, US
Contact	Declan Hynes
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...

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k212648/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026