

K063720 VITROS IMMUNODIAGNOSTIC PRODUCTS TOTAL B-HCG II REAGENT PACK, CALBRATORS, RANGE VERIFIERSApr 9, 2007
115 days to decisionK063720 · Product code: **DHA** · Chemistry
Source: <https://www.510kdatabase.net/k063720/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Human Chorionic Gonadotropin (DHA)
Date received	Dec 15, 2006
Decision date	Apr 9, 2007
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

Ortho-Clinical Diagnostics is an in vitro diagnostics company specializing in clinical laboratory testing and immunoematology. 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/k063720/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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