

K062838 VITROS TROPONIN I ES ASSAY, INCLUDING REAGENT PACK, CALIBRATORS AND RANGE VERIFIERS, MODELS 680 2301, 2302 AND 2303Dec 19, 2006
89 days to decisionK062838 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k062838/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Sep 21, 2006
Decision date	Dec 19, 2006
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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