

K060632 VITROS IMMUNODIAGNOSTIC PRODUCTS NT PRO-BNP REAGENT PACK,CALIBRATORS,RANGE VERIFIERS,680 2156,680 2157,680 2158

Jun 6, 2006
89 days to decision

K060632 · Product code: **NBC** · Chemistry
Source: <https://www.510kdatabase.net/k060632/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Natriuretic Peptide (NBC)
Date received	Mar 9, 2006
Decision date	Jun 6, 2006
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho-Clinical Diagnostics, Inc.
Location	Rochester, NY, US
Contact	LEAH DE WATER
510(k) history	106 submissions · 104 cleared · 1997-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k060632/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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