

Premarket Approval (PMA) Package for
Dockets Management Branch

PMA Number P030024
Docket # 2004M-0341

Ortho-Clinical Diagnostics, Inc.
Vitros Immunodiagnostic Products Anti-HBc
Reagent Pack and Vitros Immunodiagnostic
Products Anti-HBc Calibrator

Includes:

Approval Order
Summary of Safety and Effectiveness Data (SSED)
Labeling

2004M-0341

AAV 1