

**Premarket Approval (PMA) Package for
Dockets Management Branch**

**PMA Number P030026
Docket # 2004M-0356**

01/10/04 10:10:00 AM

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

Includes:

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

2004M-0356

AAVI