

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

**PMA Number P040008
Docket # 2004M-0342**

**bioMerieux, Inc.
VIDAS TPSA assay**

Includes:

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

2004M-0342

AAV 1