

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

**PMA Number P040004
Docket # 2005M-0109**

**Bayer Healthcare, LLC
ADVIA Centaur® HbC Total ReadyPack Reagents
and
ADVIA Centaur® HbC Total Quality Control
Materials**

Includes:

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