

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

**PMA Number P890064/S009
Docket # 2004M-0147**

**Digene Corporation
Digene Hybrid Capture 2 (HC2) High-Risk HPV
DNA Test**

Includes:

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

2004M-0147

CR 1