

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

**PMA Number P040012
Docket # 2004M-0388**

**Guidant Corporation
ACCULINK™ Carotid Stent System and RX
ACCULINK™ Carotid Stent System**

Includes:

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