

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

**PMA Number P000054  
Docket # 2004M-0249**

**Wyeth Pharmaceuticals, Inc.  
INFUSE® Bone Graft**

**Includes:**

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

*2004M-0249*

*AAV1*