

**Premarket Approval (PMA) Package for** SEP 2 10 34  
**Dockets Management Branch**

**PMA Number P040005  
Docket # 2005M-0387**

**DakoCytomation Denmark A/S  
DakoCytomation Her2 FISH pharmDx™ Kit**

**Includes:**

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

*2005M-0387*

*AAVI*