

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

**PMA Number P040011  
Docket # 2005M-0388**

**DakoCytomation California, Inc.  
DakoCytomation c-Kit pharmDx™ Kit**

**Includes:**

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

*2005M-0388*

*AAV1*