

Premarket Approval (PMA) Package for 0898 MAY 21 P1:33
Dockets Management Branch

**PMA Number P040030
Docket # 2005M-0160**

**BioGenex Laboratories, Inc.
InSite™ Her-2/neu kit**

Includes:

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

2005M-0160

AAV1