

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

**PMA Number P030030
Docket # 2005M-0089**

**Genyx Medical, Inc.
URYX® Urethral Bulking Agent**

Includes:

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

2005M-0089

AAV 1