

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

**PMA Number P020021
Docket # 2004M-0495**

**Axcan Scandipharm, Inc.
Wizard X-Cell™ Photodynamic Therapy Balloon
with Fiber Optic Diffuser**

Includes:

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

2004M-0495

AAV 1