

## Regulatory Strategy - Pathway Selection

An effective **regulatory strategy** accelerates market entry and reduces costs

### 6-Step Strategy Development Roadmap



#### Fast Track

510(k), Expedited review



#### Balanced Pathway

De Novo, Class IIa



#### Comprehensive Pathway

PMA, Class III



**Key Point:** Collaborating with regulatory experts in the early stages to establish a strategy reduces the risk of development direction changes and increases approval success rates