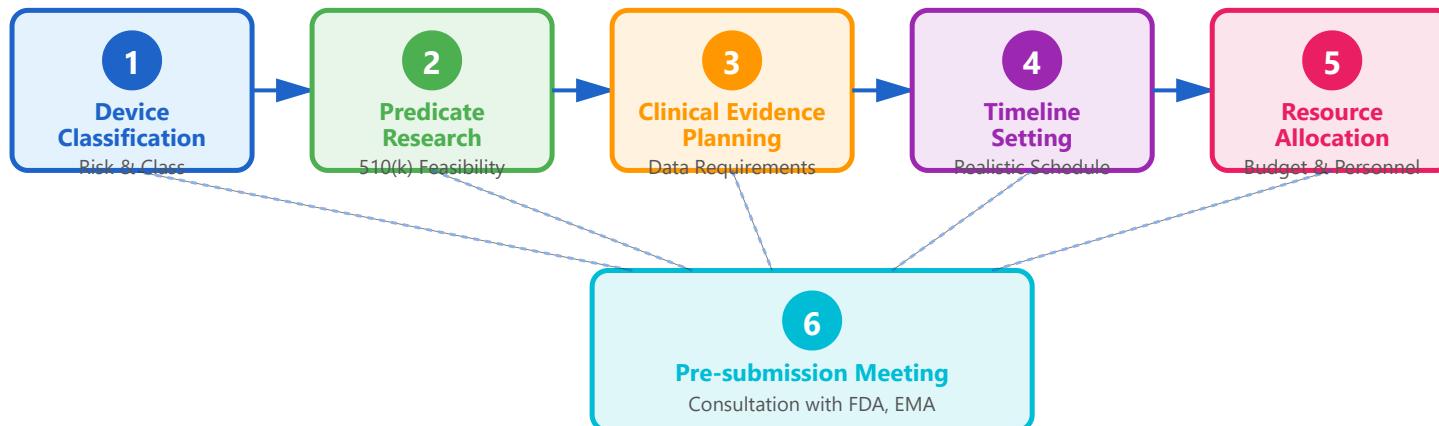


## Regulatory Strategy - Pathway Selection

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