PMA (Premarket Approval) - High-Risk Devices

PMA is the **most stringent regulatory pathway** required for **Class III high-risk medical devices**

📋 Required Submission Materials

- Pre-clinical research data
- Clinical trial results
- Manufacturing and quality control information
- Labeling and instructions for use
- Risk-benefit analysis

⏰ Review Timeline

- Standard: 180 days (filing decision)
- Total process: 1-3 years
- Advisory panel review possible

510(k) 🚀 PMA Comparison 🔬

Comparison Item	510(k) Clearance	PMA Approval
Evidence Level	Substantial Equivalence (Substantial Equivalence)	Safety & Effectiveness (Safety & Effectiveness)
Clinical Trials	Optional	Required
Review Timeline	~90 days (3 months)	~180 days (1-3 years)