Part 1/3:

FDA Regulatory Pathways

1. FDA AI/ML Pathway - Adaptive Regulatory Framework
2. 510(k) Clearance - Substantial Equivalence Certification
3. PMA Approval - High-Risk Device Approval
4. De Novo Classification - New Device Classification
5. Software as Medical Device (SaMD)
6. Predetermined Change Control Plan (PCCP)
7. Clinical Validation Requirements