Regulatory Approval Updates (Regulatory Approval Updates)

📋 Regulatory Requirements

- FDA 510(k) or De Novo clearance
- EU MDR (Medical Device Regulation) compliance
- Clinical validation data submission
- Change Control Protocol

🔄 Model Update Approval

- Minor Updates: Simplified procedure (30 days)
- Major Updates: Full reapproval required (6-12 months)
- Predetermined Change Control Plan
- Real-time monitoring and reporting

📄 Documentation Requirements

- Detailed change log
- Performance validation report
- Risk Assessment

- Maintain Audit Trail