

# Designing and Implementing a Strategic Regulatory Plan for Market Clearance

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# Designing a Plan

## Implementing the Plan

### Avoiding Problems

# Risk Management

- Especially important for technologically advanced and/or novel device designs
- Regulatory risk reduction
  - Reducing risk through regulatory pathway planning
- Resources management
  - Tasks
  - Time
  - Personnel, External resources
  - Budget
- Communication among team members and stakeholders
- Help from experts



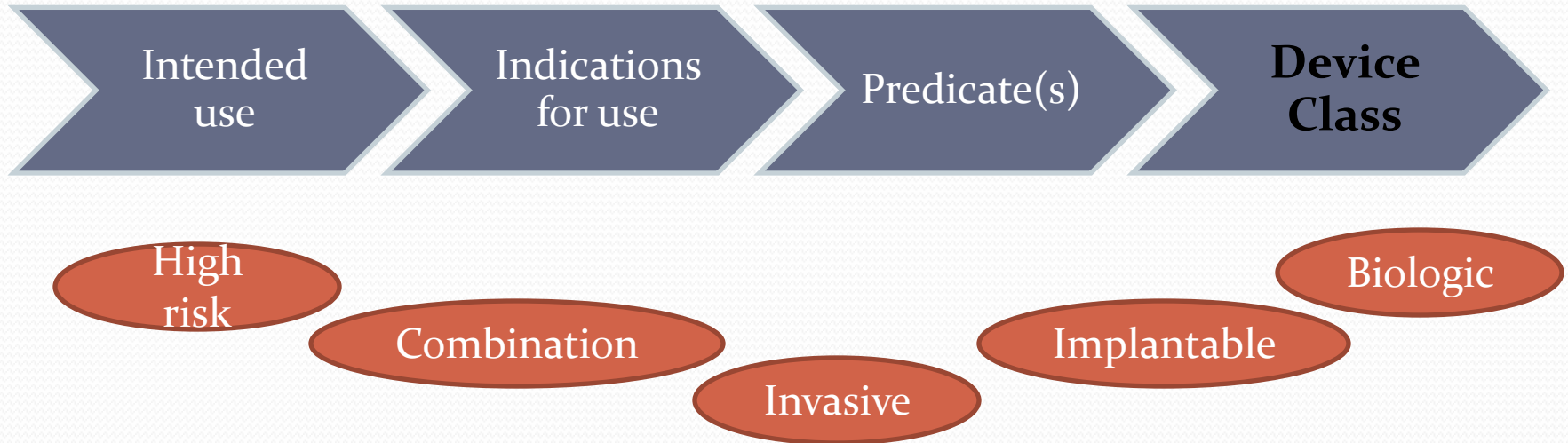
# Initial Regulatory Planning

- Product description (intended use, features)
- Initial worldwide markets
- Device classification
- Standards requirements
- Product verification and validation tests
- Software complexity (minor, moderate, major)
- Preclinical tests
- Clinical tests (significant vs. non-significant risk device)
- Labeling
- Quality system requirements (manufacturing plans)
- Facility/product registrations
- FDA interactions / regulatory audits
- Exporting



# Defining Regulatory Framework

- Product Description



# Classification - US

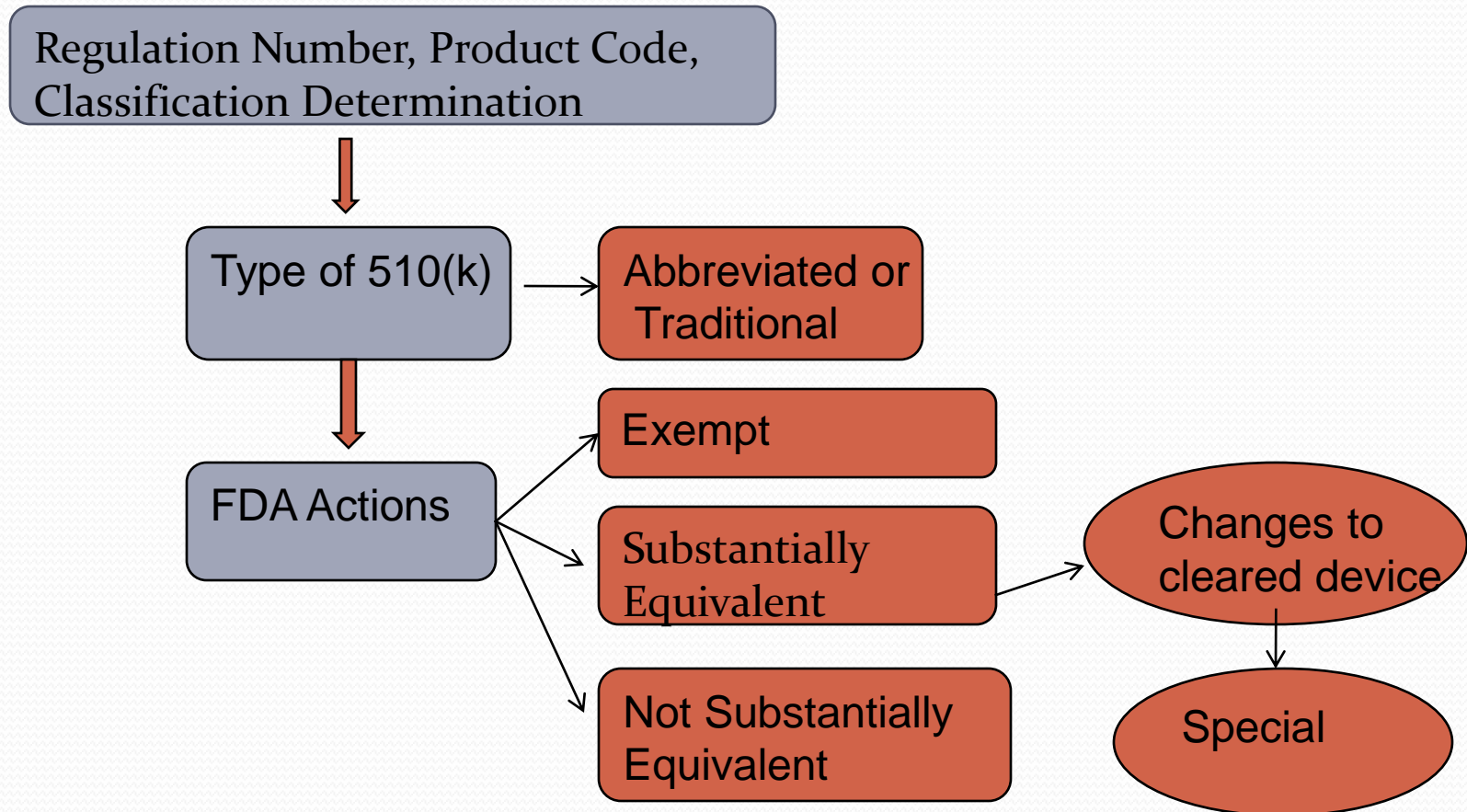


Class I - Exempt

Class II - 510(k)

Class III - PMA

# 510(k) Premarket Notification Path



# Product Testing

*“In God we Trust, All Others Bring Data”*

# Defining Test Requirements

- Tissue contact - Biocompatibility
- Sterilization
- Electrical testing
- Diagnostic
- Preclinical
- Clinical, IDE
- Software
- Performance specifications - Functional
- Standards
- Benchmarking against predicates or similar devices

Identify similar devices

Review standards, 510(k) summaries

Develop test plan  
Budget resources  
Develop schedule  
Communicate  
Coordinate

# Plan Maturity

EO Sterilization Validation

10 months

Plan, Protocol, Build product, Execute

8 months

Parallel Path

6

months

# Executing the Plan

*Resources, Time, Budget*

# Strategic Planning

Time to Complete V&V



Time to Manufacturing



Time to Human Trials



Time to Submission



Time to Market

# Regulatory Pitfalls

# Fail to Plan, Plan to Fail

- Underestimating the clinical significance and risk/benefit of a device
- Not clearly identifying product design features and testing those features for safety and efficacy
- Not clearly identifying study and protocol objectives, endpoints and means of measure
- Not planning for undesirable test results, contingency plans
- Not understanding the difference between ‘Substantial Equivalence’ and ‘Safety and Efficacy’ in regulatory applications
- Underestimating the level of detail and data required to get a submission out on time
- Underestimating the level of detail required in clinical studies
- Not planning enough time for software development and testing; underestimating software documentation requirements
- Not planning for outcomes such as ‘Not Substantially Equivalent’

# FDA Interactions



- 1- Not talking with FDA early and often enough
- 2- Not having a well thought out plan before meeting with FDA
- 3- Not having representation to FDA

**Thank you!**