HCSS / CPS Strategic Priorities

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The Challenge

- Devices have evolved from analog to digital
- Devices are transmitting data on networks
- Devices are aggregating data
- Devices will be sharing data
- Devices will be interoperating
- Devices will be systems of systems
- Devices will be omni-present
- Devices will challenge current concepts – biological
  - Software is now ubiquitous in medical devices
  - Software complexity in devices is increasing
FDA Strategic Priorities in HCSS

- Formal methods based design
  - Device software/system safety modeling
  - Component composition
  - System/software certification/assured verification
  - Forensic analysis
  - Engineering tool foundations
- Cyber physical systems
  - Integration of computer and information-centric physical and engineered systems
- Architecture, platform, middleware, resource management
  - Interoperable Plug and Play devices
  - Vigilance and trending systems
- Component-based foundations for accelerated design and verifiable system integration
FDA Strategic Priorities in HCSS (cont’d)

♦ Infrastructure for Medical Device Integration & Interoperation

♦ Model based development

♦ Component based design frameworks

♦ Patient modeling & simulation

♦ Adaptive patient-specific algorithm

♦ Requirements & metrics for certifiable assurance & safety
The Strategy

Software Development Lifecycle Process

- Analysis
- Design
- Code
- Test

Artifacts
- Requirements
- Hazard Analysis

Results
The Strategy

Software Development Lifecycle Process

Analysis

Design

Code

Test

Artifacts

Requirements
Hazard Analysis

Formal Analysis
& Design

Results

Static Analysis

Flight Recorder
Simulation

Certification

Safety Case
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THE END