



Transforming Critical Care™

Interoperability Through Integration

Integrated Medical Systems, Inc.

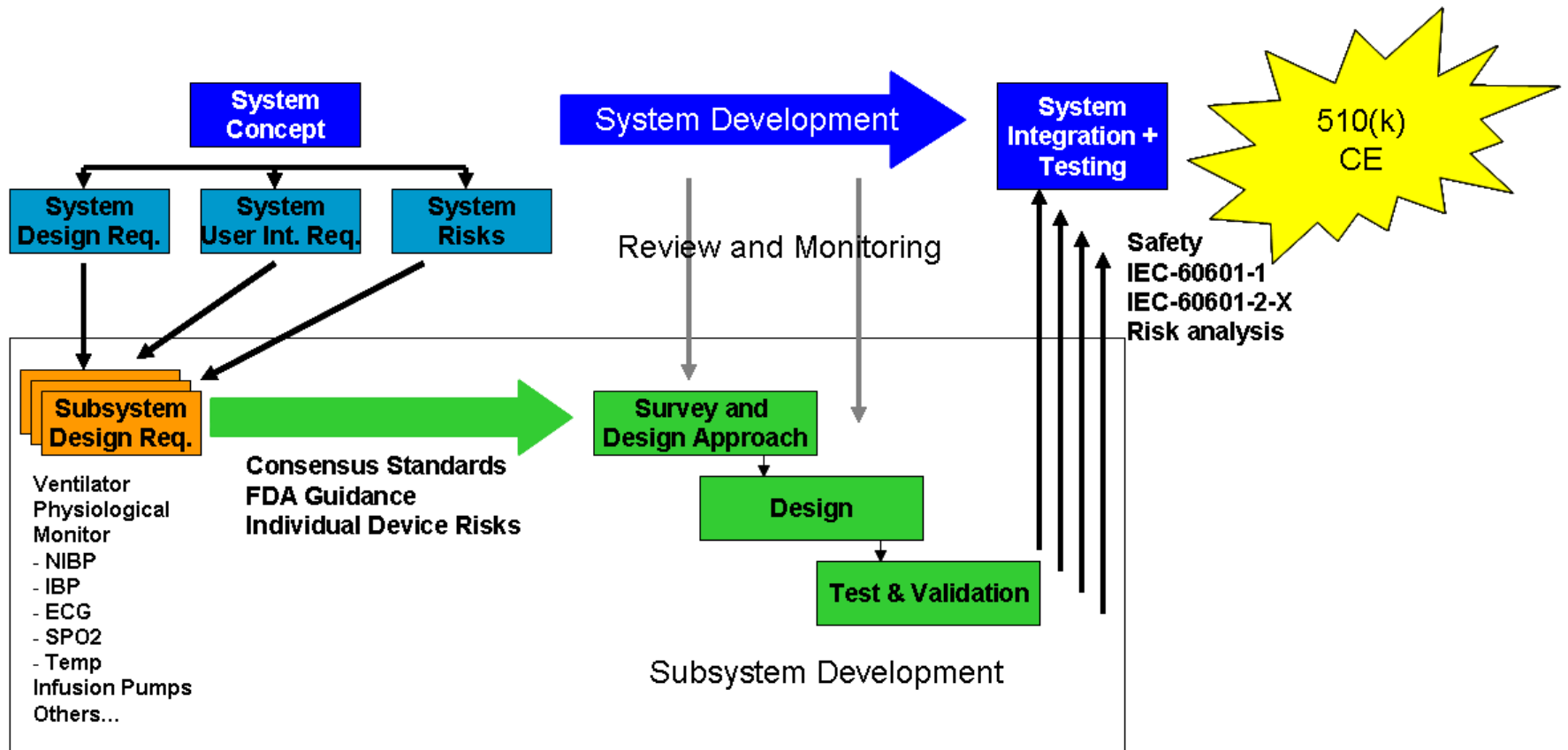
Problem





- **Use ‘Systems Integration’ to design a medical device**
 - Art and Science of Combining Multiple Pieces of Equipment into ONE
- **Benefits of ‘Systems Integration’**
 - Ease of Use
 - Safety (Operator & Patient)
 - Easier to Maintain and Upgrade
 - Increased Reliability
 - Reduced weight, volume, cost and clutter

Design Approach





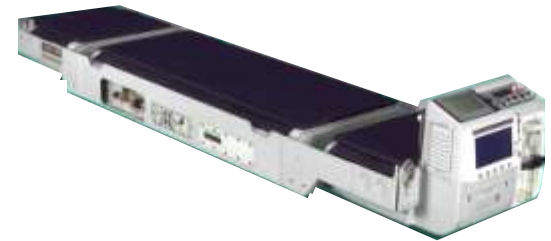
- **Classification of a Integrated Device**
 - Multiple Intended Uses
 - Multiple Device Classifications
 - Risk Management
- **Application of Consensus Standards**
- **Software**
 - FDA Guidance
 - ANSI/AAMI/IEC 62304:2006
- **Labeling**



- **Single Integrated Device**
 - Multiple Components
 - Class II Devices (Class III with inclusion of AED)
 - Software Key Element
- **Comprehensive 510(k) Submission**
 - Consensus Standards Compliance
 - Guidance Documents
 - Software Guidance Document
 - Hazard Analysis/Risk Management
 - Complete Labeling

Two (2) 510(k) Cleared/CE Marked Integrated Medical Device Systems:

- LSTAT (K965117) Cleared 1998
- LS-1 (K082256) Cleared 2008



Advanced Information Architecture



LSTAT Handheld



Handheld / PDA



Nurse's Station



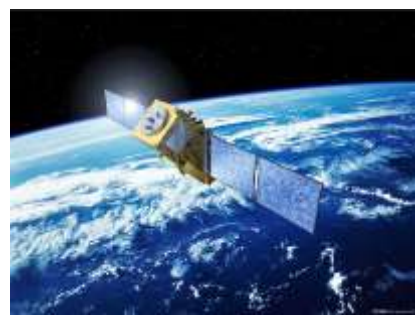
Patient Record Systems



Clinical Display Systems



Telemedicine



Closed Loop Control

