We address the entire development process, from Industrial Design and Human Factors Engineering through Design Engineering, Verification, and Transfer, all with Quality and Compliance. Our staff offers the expertise and experience to solve your development challenges efficiently, according to your specific needs. We can help you optimize your budget and shorten development times for your Class I, II, or III device through the use of the latest tools and technologies. If you have a technical issue or other problem that is delaying your current project, we have the resources and expertise to jump right in and get your project back on track. 

Sterling helps medical device companies bring innovative products to market – electromechanical, mobile, wearables, and all flavors of software.

Compliant with: 21 CFR 820, IEC 62304, ISO 14971, IEC 60601, IEC 62366

ISO 13485 Registered
Experience Across Disciplines

- **System Design**
  - DFM / DFT / DFA
  - Design for Six Sigma
- **Electromechanical Engineering**
  - Analog Design
  - Digital Design
  - RF Design
  - Design for EMC/EMI
  - Mechanical Design
  - Test Fixture Development and Validation
- **Software Engineering**
  - Firmware
  - Application
  - Mobile (Android, iOS)
  - Cloud - Website - Web Services - Mobile and Workstation Integration via Cloud Connectivity
  - Operating system customization for medical use
- **Risk/Hazard Planning, Analysis and Mitigation**
  - FEA Analysis - Stress Structural, Fluidic, Thermal Analysis
  - FMEA & Fault-tree Analysis
- **Verification and Validation**
  - Wireless Communications
    - RF
    - Bluetooth/BLE
    - Wi-Fi
- **Human Factors Engineering**
  - Contextual Inquiry / User Research
  - Formative Studies
  - Summative Testing
- **Industrial Design**
  - Concept Ideation
  - Rapid Visualization
  - Usability & Ergonomics
  - Brand Identity
- **Interaction Design**
  - User Experience / User Interface
  - Task Analysis
  - Wireframing & Visual Design
  - Usability Testing
- **Prototyping**
  - 3D Printing (SLA, FDM)
  - Appearance Models
  - Pre-Evaluation Models

**Advantages**

- U.S. Based Full Time Engineering Staff
- Validated Tools, Staff Trained
- Experts in Regulatory Concerns
- Extensive IT Infrastructure/Real-time Backup
- Leading Edge Project Management and Collaboration Tools
  - Polarion and Skype for Business
- Engineering/Design Focused with Design for Manufacturability
- Transparent, Customer Focused
- Work with Companies from Startups to the Well Established
  - Startups leverage our ISO certified QMS, IT infrastructure, and experience.
  - The well established utilize our talent and expertise to get the job done right.
  - We "Do What It Takes" to make our clients successful.

**HS DESIGN, INC.**

**STRATEGY & PLANNING**
- Contextual Inquiry
- Technology Assessment
- Project Planning
- Risk and Feasibility
- Regulatory

**IMMERSION & DEFINITION**
- User Research
- Design Inputs
- System Architecture
- Concept Ideation
- Proof of Concept

**DESIGN & DEVELOPMENT**
- Design & Engineering
- Applied Human Factors
- Formative Evaluation
- Design Outputs
- Design Verification

**PRE-PRODUCTION**
- Product Documentation
- Prototype Builds
- Pre-manufacturing Support
- Design Finalization
- Summative Usability Testing
- Validation / Testing

**REALIZATION**
- Design Transfer
- Production Ramp
- Market Launch

* Usability: "characteristic of the USER INTERFACE that establishes EFFECTIVENESS, EFFICIENCY, ease of USER learning and USER satisfaction."

(AAMI / ANSI / IEC 62366 - FDA HF Guidance for User Research in Medical Device Design)
Call us at **201-227-7569 x2**

or visit [sterlingmedicaldevices.com](http://sterlingmedicaldevices.com) to get your free customized analysis

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