Focus on Cardiac Devices

with

ProvenProcess
MEDICAL DEVICES
We are focused

- FDA Class II and III therapeutic and diagnostic device product development and manufacturing
- A mature, well-developed ISO-13485 quality system
- Efficient and effective, Best-in-Class for rapid Time-to-Market

…and experienced

- Exclusively focused on medical devices since 1994
- Medical capital equipment, patient monitoring, implantable and disposable devices, in-vitro diagnostics
- Success with devices in accordance with FDA and MDD, AIMDD and IVDD
**Who We Are**

**We are trusted**
- Customers include industry leaders: Boston Scientific, & Johnson, Medtronic, Pfizer and others
- Emerging companies
- High customer return rate
- ISO 13485:2003 certified
- FDA registered & successfully audited

**Staff resources**
- Engineering
  - Design and Development
  - Quality
  - Manufacturing
- Full Quality Assurance oversight
- Regulatory support
- Manufacturing assemblers and technicians
Broad cardiac device experience

- Cardiac monitoring, implanted and external
- Cardiac assist devices
- Cardiac rhythm management
- Artificial heart drive equipment
- Robotic assisted electrophysiology
- Specialty catheters and access needles
Successful designed and developed products

- Total artificial heart pneumatic drive unit
- Remote catheter manipulation equipment
- Implantable cardiac monitor
- Implantable left ventricular assist device
- Intra-aortic balloon pump pneumatic driver
- Programmer for implantable pacemakers and defibrillators
- Cardiovascular kits and trays

Examples of these Proven Process designed, developed and manufactured products are in the following slides…
Total artificial heart pneumatic drive unit

- Advanced pneumatics and vacuum servo control
- Redundant mains and battery power sources
- Single board computer platform enables highly refined User Interface
- Touch screen graphical user interface (GUI) for rapid set-up and unequivocal data display
- Hard-wired logic operation for electronic back-up
- Verification to complete suite of IEC 60601 for Safety, EMC, User and Usability, Software, and Alarms and Notifications
- Shipping packaging and shipping verification
Remote catheter manipulation equipment

- Unique design, compatible with major electrophysiology catheters
- Remote fine-control catheter operation after initial placement
- Handheld controller simulates catheter controls with virtually no learning curve
- Multi-axis motion
- Software-free hardware (FPGA) state machine electronics
- High volume/low cost sterile field disposables design
Implantable cardiac monitor

- Embedded arrhythmia detection algorithm
- Wireless data and alert to remote receiver
- Embedded, sealed electrodes
- Electronic hardware and software optimization
- Hermetic package
Implantable left ventricular assist device

- Novel combination brushless linear and rotary motor electromagnetic design
- Low shear hydrodynamic blood bearing design
- Pump piston trajectory control circuit design
- Stable flow-through blood pressure sensor
- Physiologic control algorithms
Programmer for implantable pacemakers and defibrillators

- Self-contained, battery operated handheld
- Easy user navigation
- Embedded microprocessor hardware and software
- Wireless telemetry operation
- Medical device software validation
Intra-aortic balloon pump pneumatic driver

- Valved plenum topology
- Pressure and vacuum balance control
- Multiple over-pressure safety mechanisms
- Embedded EKG and blood pressure monitoring
- Portable for destination therapy
Cardiovascular kits and trays

- Clean room assembly (ISO Class 7)
- Various manufactured kits to support current products
- Pouch, tray and tray-within-a-tray designs
- Custom kit assembly to application and specification
- Sterile seal design and seal PQ
- Sterilization validation
Our offered services for the entire cardiac product life cycle

Concept to Customer SM

- Product definition
- Concept design
- Prototype development
- Design for manufacturing

Design & Development

Verification & Validation

Contract Manufacturing

- Product verification & process validation
- Domestic & international compliance

- FDA registered
- ISO 13485 certified
- Pilot & full scale manufacturing
Our “Proven Process” in six phases

1. Design Input & Project Planning
2. Concept & Feasibility
3. Detailed Design & Prototype
   - Manufacturing Process Design
4. Pilot Manufacturing & Design Validation
5. Transfer to Manufacturing & Process Validation
6. Commercial Manufacturing & Product Support

Design Control

Process Control
Mechanical Engineering

- Mechanical/electro-mechanical mechanisms
- Molded and extruded component design
- Fluidics design, both macro and micro
- Pneumatic drive and control
- Biocompatible materials selection
- Finite element analysis
- Computational fluid dynamics analysis
- Sterile and non-sterile packaging
- Rapid prototyping
Electrical & Electronic Engineering

- IEC 60601 medical grade electronics
- Physiological data acquisition
- Embedded microprocessor devices
- Application specific integrated circuits (ASIC, FPGA, Gate Array, etc.)
- Wireless communication including inductive, MICS, Bluetooth, and 802.11
- Digital signal processing (DSP) solutions
- Printed circuit board design
- Battery operated and low power devices
- Motor and motion control
- Analog and digital design and simulation
Software and Firmware Engineering

- Medical grade software using ANSI/IEC 62304 lifecycle
- Compliant with FDA guidance's and international standards
- Major languages include C, C++, C#, Visual Basic, and assembly languages
- Software for Windows, Linux, QNX and other major RTOS
- Embedded microprocessor software/firmware
- Digital signal processor software
- Automated test equipment software
- Independent software V&V
• Design verification
  • Risk management/mitigation (ISO 14971)
  • Functional and performance verification
  • Electrical safety and EMC per IEC 60601
  • Biocompatibility verification per ISO 10993
  • Sterility verification per ISO 11607
  • Software validation
  • Environmental operation and storage
  • Product packaging transport verification

• Process validation
  • Equipment and process IQ/OQ/PQ
  • Process FMEA
  • Process capability analysis
• Mechanical and electronics assemblies
• Disposables assembly and packaging
• Sterile and non-sterile product packaging
• Medium volume, high mix production capacity
• Class 10,000, ISO Class 7 Clean Room assembly
• Incoming inspection and warehousing controls
• Enterprise Resource Planning (ERP) tracking
• Supply chain management including Approved Supplier Program
• FDA registered and ISO 13485 certified manufacturing and assembly
Thank You!