



## CLASS III REMEDIATION

**SQUARE-1 SUCCESSFULLY ADDRESSES LARGE SCALE DEVICE MANUFACTURERS REGULATORY WARNING LETTER VIA COMPANY WIDE QUALITY MANAGEMENT SYSTEM OVERHAUL AND SUPPLIER ACCOUNTABILITY MATRIX**

### **SITUATION**

FDA issued 483 due to product field failures posing life threatening risks to implant patients

### **TASK**

Identify systems level issues across 6 business units including external field failures, develop enterprise wide remediation plan, implement plan and corrective actioning

### **ACTION**

Identified issue, built company wide attack plan while deploying 23 SME's across 6 business units using flex workforce

### **RESULTS**

Successfully averted plant closure by addressing FDA citations, developed new enterprise wide SOPs, supplier full cycle CAPA processing, implemented new automated internal complaint handling system

### **SME TEAM:**

Within two weeks Square-1 deployed: 7 Quality Eng, 1 Interim Site Quality Director, 1 IT Project Mgr, 4 Manufacturing Eng, 3 Complaint Handling, 3 Regulatory Affairs, 3 Project Mgr, 1 Configuration Mgr

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