Job: Systems Engineer
Location: Cleveland, OH

Position Summary:
The Systems Engineer is an Exempt/Full-Time position that works alongside the development team to ensure product specifications are achieved and in compliance with medical regulatory practices and company procedures. The role assists in system risk analysis, as well as identification, prioritization, and documentation of customer needs and requirements. The Systems Engineer develops system and sub-system interface requirements that assure the completed system meets required functionality. Together with the development team, the Systems Engineer is responsible for investigation, evaluation, and selection of the best system structure and documentation.

Responsibilities/Duties:
● Responsible for overall system engineering / testing for a complex electromagnetic surgical navigation product platform.
● Develops/maintains system architecture and interface requirements for the products, based on technology and platform strategies.
●Defines subassembly interfaces and subassembly requirements to both internal and outsourced design teams.
● Implements and tests the product platform to ensure high quality, robust behavior and safety in accordance with medical device regulatory standards and customer requirements.
● Responsible for daily system engineering activities including leading issue resolution and communication across teams in order to deliver results on-time and on-budget.
● Develops/maintains the risk management file in accordance with ISO 14971 and ensures product safety in accordance with IEC 60601-1 and its appropriate subparts.
● Works with other team members and functions to execute design reviews of complex Medical Devices.
● Drives structural design documentation and plans by applying engineering best practices.
● Conducts impact analysis for design changes and implements necessary actions including estimates of impact to time, budget, and scope.
● Effectively coordinates test activities throughout the project to drive efficiency in V&V in collaboration with the regulatory resource to ensure a complete and effective 510(k) submission.
● Understands and follows quality and product development processes.
● Incorporates business, market, industry, and competitive knowledge into technical solutions.
● Determines required tasks and completes on time with minimal supervision.
● Identifies and communicates potential risks with appropriate mitigations.
● Synthesizes complex information gathered from a variety of sources and disseminates to others.
● Additional duties as assigned.

Minimum Qualifications, Education, and Experience Required
Education and Experience:
● Bachelor’s degree with 3+ years of medical device development experience is highly desirable
● Involvement with medical device regulatory standards such as IEC 60601, IEC 62304, ISO 14971 and ISO 13485 including experience with system risk/hazard analysis
● Experience with FDA 510(k) product/testing requirements
● Excellent IT/computer skills and a willingness to learn new tools as they become relevant
● Flexibility and ability to self-start on new challenges, problem-solving with minimal supervision
● Ability to work efficiently on multiple tasks with deadlines
● Ability to work in a diverse team with members of varying education and experience levels
● Creative/innovative, able to rapidly problem-solve and work well given typical project schedules
● Superb organizational and multitasking skills as well as strong written and verbal communication skills
● Familiarity with ISO and IEC standards pertaining to medical devices

Abilities:

● Proficiency with functional analysis and cascading down from user level to subsystem/ component level of customer requirements
● Experience working in Quality or Regulatory capacities in the medical device industry
● Skilled in developing test plans and validation protocols in a regulated environment
● Capability of using automated software testing tools
● Familiarity with numerical analysis and methods
● Ability to work effectively in a multidisciplinary team while maintaining independence from technical development
● Strong analytical skills and willingness to develop understanding of relevant concepts in medicine and mechanical, electrical, and materials engineering
● Demonstrable experience in performing risk assessment, software validation and testing

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