Job Description

JOB TITLE: PRINCIPAL PRODUCT DEVELOPMENT ENGINEER, TOTAL JOINTS	
BUSINESS DIVISION: WISHBONE MEDICAL INC	**Status:** FULL-TIME
DEPARTMENT NAME: NEW PRODUCT DEVELOPMENT	**Type**: SALARY / EXEMPT
PREPARED BY: HUMAN RESOURCES	**DATE**: 2/5/2021
WORK LOCATION: CORP - WARSAW	**REPORTS TO:** DIRECTOR OF PRODUCT DEVELOPMENT

SUMMARY: The position of Principal Product Development Engineer, Hips is responsible for design and development of pediatric total hip implants and instruments (single-use and reusable) from concept through market introduction, and ensuring that designs meet performance specifications, regulatory and manufacturing requirements.

ESSENTIAL DUTIES AND RESPONSIBILITIES: *(includes the following but other duties may be assigned)*

- Design and develop medical pediatric total hip implants and instruments (single-use and reusable), from concept through market introduction. Ensure that designs meet performance specifications, regulatory and manufacturing requirements.
- Product Owner for new product development projects using Agile Scrum format. Create and manage project backlogs and user stories. Create and manage project release burndowns and proactively report project status to personnel
- Work with surgeons, marketing and sales to define and refine design inputs, generate design concepts and prototypes independently, perform meaningful and timely design evaluations (such as tolerance analysis, FEA, simulated use testing, dry labs and wet tissue labs etc.), and oversee generation of documentation of clinical and surgical technique observations to create meaningful design solutions.
- Generate innovative concepts for new medical device designs to satisfy clinical requirements. Lead and participate in concept generation activities, including brainstorming sessions.
- Develop CAD models and drawings of medical instruments (single-use and reusable), implants, and/or packaging. Includes component, subassembly, and top-level drawings.
- Maintain Design History Files (DHFs) per company procedures. Ensure that DHFs are accurate, complete and well organized.
- Conduct risk analysis activities and complete related forms – including Risk Plans, DFMEA, Risk/Benefit Assessments, Risk Reports, and others as needed – for products under development and post-production as required.
- Perform and document tolerance analysis of components and assemblies to ensure proper fit and function.
- Develop prototype devices for testing, and for evaluation during verification and validation phases. Work with internal and/or external resources to produce prototype device components.
- Conduct and/or monitor product verification and validation testing to demonstrate product safety and efficacy. Determine which testing is required to satisfy product requirements, to investigate potential failure modes, and to otherwise address the project design inputs. Develop protocols, plan testing, and perform or monitor testing. Utilize statistical methods as required to plan testing and to analyze test results. Write test reports which draw conclusions from the results.
- Ensure that all work satisfies the requirements of the company's Quality Manual, with particular emphasis on Design Control.
- Conduct Design Reviews as specified in project plans, and in accordance with company procedure.

- Prepare documentation release packages, including detail drawings, bills of material, and/or procedures. Approve Document Change Orders (DCOs) and/or Engineering Change Orders (ECOs) and obtain approvals from others as required.
- Participate in Material Review Board activities. Make decisions regarding product and material discrepancies and initiate appropriate action to prevent subsequent problems or discrepancies.

QUALIFICATION REQUIREMENTS:

- Minimum BS degree in Mechanical Engineering, Biomedical Engineering, Bioengineering, or Biomedical Engineering Technology, or related field
- 7-10 years of experience in one of these disciplines

OTHER SKILLS and ABILITIES:

- Excellent oral and written communication skills
- Ability to lead cross-functional teams in more than one project at a time
- GD&T and CAD experience with Siemens NX preferred
- Ability to meet deadlines, dependable, and self-directed
- Capable of working in fast-paced team environment

PHYSICAL DEMANDS: The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodation may be made to enable individuals with disabilities to perform the essential functions.
While performing the duties of this job, the employee is regularly required to sit and talk or hear. The employee frequently is required to stand; walk; and use hands to finger, handle, or feel objects, tools, or controls. The employee is occasionally required to reach with hands and arms. The employee must occasionally lift and/or move up to 20 pounds.

WORK ENVIRONMENT: The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of this job. Reasonable accommodation may be made to enable individuals with disabilities to perform the essential functions.
Associate will normally work in an office environment but may also be subject to high noise levels from machines, and physical hazards from moving machine parts. WHEN OVERTIME IS SCHEDULED, IT IS MANDATORY.

REVIEWED AND ACCEPTED BY:

MANAGER	*ASSOCIATE*
NAME:	**NAME:**
SIGNATURE:	**SIGNATURE:**
TITLE: Director, Product Development	**TITLE:** Principal Prod. Dev. Engineer
DATE:	**DATE:**

The above description is intended to describe the general content, identify the essential functions of, and requirements for the performance of this job. It is not to be construed as an exhaustive statement of duties, responsibilities, or requirements.