SENIOR PRODUCT DEVELOPMENT ENGINEER - PROJECT LEAD SMARTFUSE® CAGE

Posted on 1 november, 2021

Company Name Intelligent Implants

Location Göteborg

Job Description

Do you want to be part of a global and expansive medtech company at the intersection of digital health and orthopedics? Are you a curious and committed person who is driven by the opportunity to work with the best in the industry and to take great responsibility? Welcome to join Intelligent Implants helping us enable faster healing, better informed clinical decision making and ultimately better outcomes for patients.

Intelligent Implants is a fast-paced, venture-funded medical device start-up developing novel products at the intersection of digital medicine and orthopedics.

*The company's **SmartFuse®** platform is a first-of-kind, wirelessly enabled, active electrotherapeutic implant technology that uses an array of electrodes to stimulate, control, and monitor bone growth. Intelligent Implants' mission is to leverage the **SmartFuse** platform to disrupt the orthopedic implant market with a pipeline of smart implants that can accelerate bone growth, reduce healing time, and improve outcomes for millions of patients. Intelligent implants first product, the **SmartFuse Cage**, is designed to address the unacceptably high rate of non-unions in spinal fusion surgery.*

Intelligent Implants has operations in Gothenburg (Sweden) and Houston, Texas (USA).

Senior Product Development Engineer

We are looking for an ambitious mechanical engineer and project leader to manage the implantable portion of Intelligent Implant's SmartFuse system (i.e. the SmartFuse Cage). This role will report to the VP of Product development and will have primary responsibility for the design, testing and manufacturing of the implant. Initial focus will be on helping the VP of Product Development advance the current prototype design (used in large animal testing) through first-in-human (FIH) clinical trials (e.g. design freeze, manufacturing, V&V testing and clinical release for FIH).

We are looking for an individual who can contribute directly in a technical manner on day one, but can also grow quickly with the expanding responsibilities of the role as the company moves from

development phase to the clinical phase and on to the commercial phase. This individual will be expected to identify staffing/skill needs and hire and manage a small product development team.

Must have:

- 5+ years of product development experience, preferably in Class-III active, implantable medical devices (mechanical focus preferred)
- Strong project management skills (planning, executing, and identifying/managing timeline and budget risks)
- Experience with mechanical 3D CAD systems, e.g. SolidWorks
- Experience working under design controls and a quality management system
- Experience planning and executing V&V testing
- Experience managing a small product development team (1-5 people)
- High levels of initiative and self-direction
- Willingness to "do" as well as manage
- Ability to thrive in a fast-paced entrepreneurial environment

Nice to have:

- Experience with hermetic sealing of implantable medical electronics and hermeticity testing
- Experience preparing technical/engineering documentation to support FDA regulatory submissions
- Experience managing a mix of internal and external product development (e.g. development/manufacturing vendors/partners)
- Experience working in a start-up environment with limited resources
- Experience with FMEA
- Experience with FEA
- Experience implementing a quality management system and getting a device under design controls

Other:

- Position will be located in Gothenburg, Sweden
- Competitive compensation including equity and eligibility for cash bonus

What can we offer you?

You will be an important part of developing an exceptionally novel and potentially disruptive

solution to the orthopedics market, which has struggled with a lack of transformative innovation. The combination of therapeutic electrical stimulation and remote monitoring will enable faster healing, better informed clinical decision making and ultimately better outcomes for patients. You will have the opportunity to experience some exciting years watching this technology make its way to the clinic.

The potential of our solution has given us a Breakthrough Device Designation from the US Food and Drug Administration (FDA) and as one of a very few companies we have received the prestigious EIC accelerator funding, from the European Commission.

Apply today!

This recruitment is handled by our recruitment partner, Moveup Consulting AB. To apply, please send your CV and a cover letter to tom.bergqvist@moveup.se

If you have questions regarding Intelligent Implants or this open position, please contact Tom at +46 (0)733 - 87 27 22.

By submitting your application, you also consent to us storing your personal data, including CV & cover letter and that we have the right to share this information with third parties (our client). You can revoke the consent whenever you want.

Om företag

Operating at the intersection of digital health and orthopedics, Intelligent Implants is on a mission to provide solutions to some of the most pressing unmet clinical needs by developing products designed to accelerate bone healing, improve clinical outcomes and patient quality of life, and minimize the financial and human costs associated with the treatment of degenerative disc disease and other orthopedic clinical problems.

Intelligent Implants SmartFuse® technology is a wirelessly enabled orthopedics platform that has been designed to remotely stimulate, control, and monitor bone growth. The goal of the SmartFuse® system is to accelerate bone growth and provide remote monitoring of the patient to support real-time clinical decision-making. The first indication for the SmartFuse system will be for use in lumbar spinal fusions.

Earlier this year, Intelligent Implants SmartFuse® system has received a Breakthrough Device Designation by the US Food and Drug Administration (FDA). FDA Breakthrough Device designation is granted to certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal is to give patients and doctors timely access to these medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for premarket approval.

To learn more about Intelligent implants, visit www.intelligentimplants.co

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