https://cosmiic.org

Example - Early Feasibility Investigational Device Exemption

IDE Section:

Intended use

3. Intended Use

This section contains:

3.1. Proposed Indications for Use Statement

Our development efforts are directed toward eventually being able to support the following Indications for Use Statement:

The Networked Neuroprosthesis (NNP) is an implantable, configurable neuromodulation platform that provides both activation and inhibition of nervous tissue, and sensing of physiological signals.

- *The **NNP-UE (Upper Extremity) Configuration** activates nerves of the upper extremity (arm and hand), and senses motion and/or EMG in order to provide hand grasp. It is indicated for use in individuals who:*
  - *are tetraplegic due to cervical level spinal cord injury,*
  - *have adequate functional range of motion of the upper extremity, and*
  - *have sufficient intact lower motor neuron innervation of the forearm and hand muscles to generate functional movements with electrical stimulation.*
- *The **NNP-T (Trunk) Configuration** activates nerves of the trunk in order to provide trunk stability. It is indicated for use in individuals with spinal cord injury who have sufficient intact lower motor neuron innervation of the trunk muscles to generate functional trunk stability with electrical stimulation.*

3.2. Description of the Target Population

Spinal cord injury (SCI) at the cervical level can result in complete paralysis below the level of the lesion (tetraplegia), leading to extensive disability. Loss of hand and arm control, and lack of trunk stability, can severely restrict the person's ability to perform even simple activities. These individuals are dependent on caregivers for daily activities such as eating, basic hygiene, and respiratory care. More commonly, the disabled individual utilizes multiple pieces of adaptive equipment to perform the most common and critical tasks. As a result, the individual is limited in the tasks they can perform independently and limited in the environments in which they can function independently. Not surprisingly, these individuals identify the lack of freedom to be spontaneous as a key limitation of their disability [Kilgore et al., 2001].

Individuals with SCI have often sustained their injury in the second or third decade of life and can be expected to live a near normal lifespan with proper medical management [NSCISC, 2007] meaning these individuals often live with their disabilities for 40 or more years. Cervical-level SCI resulting in tetraplegia results in severe loss of independence. Patients are typically dependent on the support of others for nearly all daily activities. Cognitive faculties are generally not impacted in SCI. Therefore, these patients strongly desire increased independence in their daily lives. For individuals with mid-cervical level spinal cord injury, restoration of hand function is their top priority [Anderson, 2004]. Conventional methods, typically braces and orthotics such as the wrist-driven flexor hinge-splint, can provide limited grasp function but are often abandoned due to a variety of factors, including poor cosmesis, weak grasp force, and limited adaptability [Allen, 1971]. As an alternative, neuroprostheses provide a promising method for significant gain in hand and arm function for cervical level SCI. Neuroprosthetic systems have also been implemented to provide trunk support for improved wheelchair seating. These neuroprostheses provide the user with a greater amount of independence, thus improving their opportunity for gainful employment and a higher quality of life.

An individual with chronic SCI will generally maintain stable health for many years. The injury itself is generally not progressive. However, the continued disuse of the paralyzed portion of the body can lead to muscle atrophy, overall loss of conditioning, chronic infection or susceptibility to infection, pain, and joint contractures. Although electrically stimulated movement alone does not resolve all of these comorbidities, it can prolong the health of the individual.

SCI is a chronic disease with no cure. Significant recovery of motor function can be expected in the six months following injury, with significantly lesser functional improvements from six to 24 months following injury. There is, at present, no treatment that has been demonstrated to restore function permanently. Thus, without this intervention, the continued state of paralysis is assured.

3.3. Rationale for a Networked Neuroprosthesis

Neuroprosthetic devices are powerful tools providing functional enhancement for individuals with central nervous system disorders, such as spinal cord injury and stroke. Life sustaining and enhancing independent functions such as breathing, standing, walking, grasping, reaching, micturition, and defecation have all been clinically demonstrated using neuroprostheses. Existing implanted neuroprosthetic systems utilize considerable external powering and signal processing, and each system must be customized to the specific application for which it is intended. This limitation severely hampers research progress in the field, as investigator teams must independently develop hardware and software prototypes in order to study their concepts in human clinical trials. Moreover, it significantly delays the introduction of new concepts in restored function to the end user, and effectively requires users to choose one restored function over another, rather than benefitting from multiple functions simultaneously.

The CWRU Networked Neuroprosthesis (NNP) system was designed with the goal of providing *multiple* restored functions to people with spinal cord injury. The NNP uses a network of small implanted modules, distributed throughout the body, and linked to a centralized power source. The modules are connected through a network cable that distributes power to each module from a central rechargeable lithium-ion battery. Each module contains processing capabilities, communicates with other modules via the network cable, and is reprogrammable over the network using a central wireless transcutaneous link. The NNP is extremely flexible and can be scaled to meet the technical needs of a broad range of neuroprosthetic applications through the selection of the appropriate modules providing the means for broader clinical application of neuroprostheses.