NSR Summary – Sparrow Link

This device study is one that does not meet the definition for a significant risk device (SR) device study and therefore falls into the non-significant risk (NSR) device classification under the current FDA guidelines. According to the FDA, under 21 CFR 812.3(m), an SR device means an investigational device that:

1. Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
2. Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
3. Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
4. Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

The Sparrow Link system:

- Is non-invasive (i.e., not an implant) and does not present a potential for serious risk to health, safety, or welfare of a subject. The device is a form of transcutaneous neurostimulation similar to a transcutaneous electrical nerve stimulation (TENS) device, which are considered NSR devices.
- Does not support or sustain human life and does not present a potential for serious risk to the health, safety, or welfare of a subject.
- Is not for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and does not present a potential for serious risk to the health, safety, or welfare of a subject.
- Does not otherwise present a potential for serious risk to the health, safety, or welfare of a subject.
- Sparrow Link is based on the Sparrow Ascent tAN System is FDA cleared (K230796) and has been used in nonsignificant risk device studies on similar patient populations.

Device Description Summary

Sparrow Link is an extension of the FDA-cleared Sparrow Ascent wearable neurostimulation device (K230796). Sparrow Link is an investigational platform that allows researchers to customize the stimulation parameter output by the Sparrow Link Pulse Generator for use in studies using non-invasive transcutaneous auricular neurostimulation (tAN) therapy.

The Sparrow Link Platform is comprised of the Sparrow Link Pulse Generator, Sparrow Link Mobile App, Sparrow Link Hub, and Sparrow Link Application Programming Interface (API) (**Figure 1**). Researchers may customize the Sparrow Link Pulse Generator's device settings and stimulation output parameters by using the Sparrow Link Mobile Application of Sparrow Link Hub with the Sparrow Link API developed by Spark Biomedical, Inc.

The Pulse Generator uses off-the-shelf "AAA" batteries. Electrical stimulation is delivered through an ergonomically designed Earpiece. The Earpiece is a disposable component that includes a single flexible silver ink printed PET substrate. The Earpiece contains three embedded hydrogel electrodes. To ensure sufficient skin-contact, the surface surrounding the hydrogel electrodes is covered with a medical grade hydrocolloid adhesive. The EPG and the Earpiece are connected to each other via a cable. The PG is portable and intended to be slipped into a pocket or clipped onto the user's clothing with a belt clip holster.

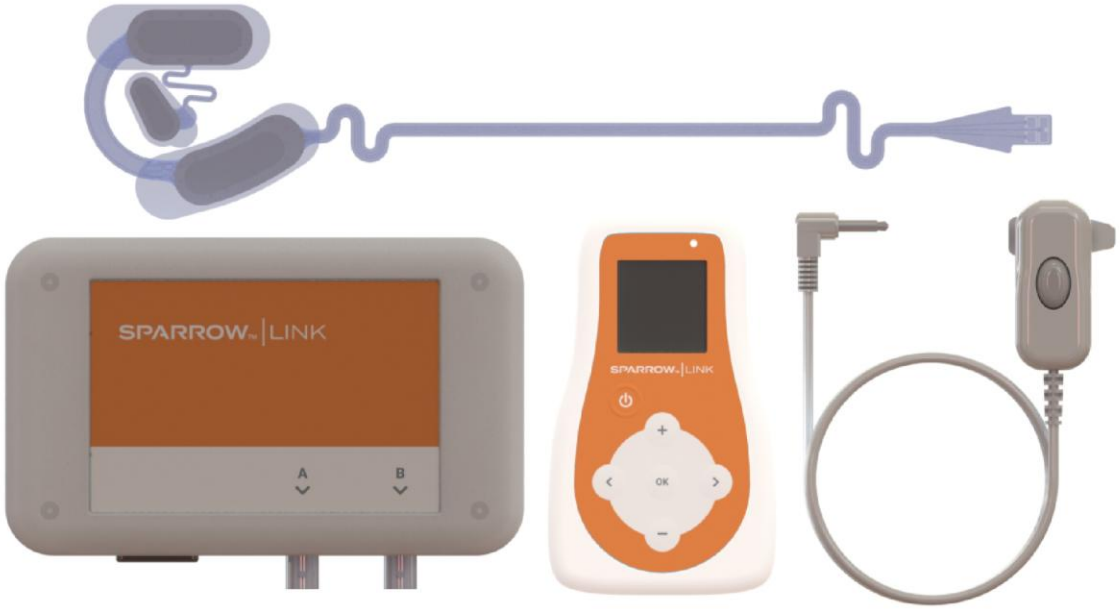

Figure 1: Sparrow Link System. Earpiece (top), Hub (bottom left), Pulse Generator (middle), Cable (bottom right)