Statistical Analysis Plan

Evoke Study: A prospective, multicenter, randomized double-blind study examining the safety and efficacy of using the Evoke™ Spinal Cord Stimulator (SCS) System with feedback to treat patients with chronic pain of the trunk and/or limbs.

Study ID: SCLSH1503
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1 Study Design

1.1 Introduction

This study is a prospective, multicenter, randomized, double-blind clinical trial designed to assess the safety and efficacy of the Saluda Medical Evoke Spinal Cord Stimulator (SCS) System with feedback control for the treatment of subjects suffering from chronic, intractable pain of the trunk and/or limbs. This study will compare the Saluda Medical Evoke SCS System with feedback to Control spinal cord stimulation (Saluda Medical Evoke SCS System without feedback).

The primary objective is to demonstrate non-inferiority of the Investigational mode of stimulation to Control stimulation in the primary composite endpoint for the treatment of subjects suffering from chronic, intractable pain of the trunk and/or limbs. [redacted]

1.2 Timing of Analyses

[redacted]

1.3 Randomization

[redacted]

1.4 Study Endpoints

1.4.1 Primary Composite Endpoint

The primary endpoint is a composite endpoint, where a subject is deemed a success if:

- They experience a 50% reduction in overall trunk and limb pain as determined by the Visual Analog Scale (VAS) at the 3-month visit, AND
- They have no increase in baseline pain medications within 4 weeks of the 3-month visit

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1.4.3 Additional Secondary Endpoints

[redacted]

- [redacted]
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1.5 Sample Size

[redacted]

1.5.1 Calculation

[redacted]

1.5.2 Justification for Sample Size Input Parameters

[redacted]

[redacted]

[redacted]

Table 1: [redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

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2 Planned Statistical Analyses

2.1.1 General Statistical Procedures

The following general statistical methods will be employed to assess the study data:

- [redacted]

- [redacted]

- [redacted]

- [redacted]

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  [redacted]

- [redacted]

[redacted]

2.1.2 Assessment of Baseline Characteristics

[redacted]

[redacted]

2.1.3 Assessment of Poolability

[redacted]

[redacted]

2.1.4 Analysis Populations

[redacted]

2.1.5 Handling of Missing Data in Primary and Hierarchical Analyses

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

Missing Data Sensitivity Analyses; Primary Endpoint

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2.2 Analysis of Study Endpoints

2.2.1 Primary Composite Endpoint

[redacted]

2.2.1.1 Primary Composite Endpoint; Supplementary Analyses

[redacted]

2.2.2 Hierarchical Secondary Endpoints

[redacted]

[redacted]

[redacted]

Table 2: [redacted]

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[redacted]	[redacted]	[redacted]
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[redacted]

[redacted]

2.2.3 Other Secondary Effectiveness Endpoints

[redacted]

2.2.4 Adverse Events

[redacted]

BIBLIOGRAPHY

1. [redacted]