**DE NOVO CLASSIFICATION REQUEST FOR**
**NSS-2 BRIDGE**

## REGULATORY INFORMATION

FDA identifies this generic type of device as:

> **Percutaneous nerve stimulator for substance use disorders.** A percutaneous nerve stimulator for substance use disorders is a device that stimulates nerves percutaneously to aid in the reduction of withdrawal symptoms associated with substance use disorders.

**NEW REGULATION NUMBER:** 21 CFR 882.5896

**CLASSIFICATION:** Class II

**PRODUCT CODE:** PZR

## BACKGROUND

**DEVICE NAME:** NSS-2 BRIDGE

**SUBMISSION NUMBER:** DEN170018

**DATE OF DE NOVO:** March 17, 2017

**CONTACT:** Innovative Health Solutions (IHS), Inc.
829 South Adams St.
Versailles, IN 47042

## INDICATIONS FOR USE

The NSS-2 BRIDGE is a percutaneous nerve field stimulator (PNFS) system, that can be used as an aid to reduce the symptoms of opioid withdrawal, through application to branches of Cranial Nerves V, VII, IX and X, and the occipital nerves identified by transillumination.

### LIMITATIONS

For prescription use only.

The device is contraindicated for use by patients with cardiac pacemakers, hemophilia, and psoriasis vulgaris.

The device should only be applied to healthy, clean, intact skin.

The device therapy is limited to 120 hours, after which the device is disposable.

The appliance is splash-proof but not watertight. When showering, the device must not be allowed to come into direct contact with water.

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

## DEVICE DESCRIPTION

NSS-2 BRIDGE is a device that electrically stimulates branches of Cranial Nerves V, VII, IX and X, and the occipital nerves identified by transillumination through percutaneous electrodes to aid in the reduction of opioid withdrawal symptoms. The device consists of (1) a percutaneous nerve field stimulator (PNFS; Figure 1), (2) a multi-pin wire harness percutaneous electrode array (Figure 2), and (3) a pen light for use in the transillumination technique that aids in positioning of the percutaneous electrodes (Figure 3).

**Figure 1: Percutaneous nerve field stimulator (PNFS)**

The wire harness percutaneous electrode array consists of 4 leads. The 1-1-1-4 configuration consists of three single-needle leads, and one 4-needle array (Figure 2).

**Figure 2: 1-1-1-4 Wire Harness configuration**

**Figure 3: Visualization of neurovasculature of the ear using transillumination technique**

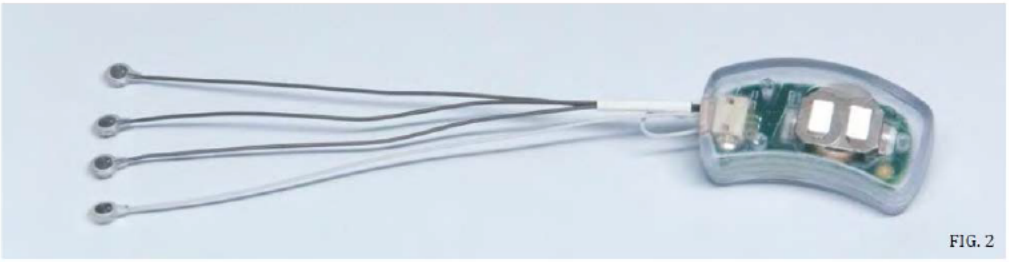


**Figure 4: Full system**

The stimulator is placed behind the ear and the percutaneous electrodes are positioned utilizing the transillumination function of the device. The transillumination technique assists in the visualization of the neurovasculature of the ear, specifically the main arterial branches and the concurrent neuro-vascular matrixes, to aid in the placement of the percutaneous electrodes near the nerve branches in the ear. The system specifications are listed in Table 1 and the output waveforms are demonstrated in Figure 5.

**Table 1: System Specifications**

| **Device Technology Description** | |
|---|---|
| **General Device Characteristics** | **NSS-2 BRIDGE** |
| Power supply | 1 x 3V battery (Type CR1220 Li) |
| Output | Max 3.2 V @ 1kΩ -10kΩ |
| Total duration of treatment | 5 x 24 hrs |
| Duty type | (b) (4) |
| Weight including battery | 5g |
| Dimensions | 36mm x 16mm x 7mm |

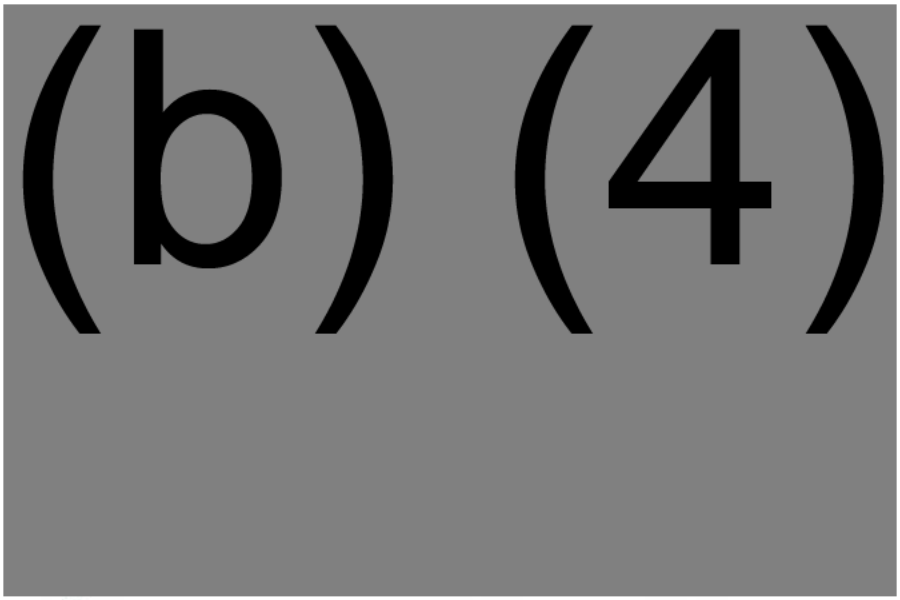


Figure 5. Representative output waveforms of the NSS-2 BRIDGE device.

The following components are part of a convenience kit sold with the NSS-2 BRIDGE:

1. Tweezers
2. Transilluminator (pen light)
3. Alcohol swab
4. Surgical marker
5. Fixation plasters
6. Foam adhesive
7. Multi-pin wire harness percutaneous electrode array

The NSS-2 BRIDGE is nearly identical to the Electronic Auricular Device (EAD) previously cleared in K140530 for a different intended use (i.e., in the practice of acupuncture). The NSS-2 BRIDGE incorporated the following technical changes from this previously cleared device:

1. The previously cleared device has a pulse sequence of 2 hours on and 2 hours off over a 120 hour run-time. The NSS-2 BRIDGE has a modified pulse sequence of 2 hours on and 1 minute off with the cycle repeating over the 120 hour run-time.

2. The original wire harness has 4 percutaneous leads: three 4-needle arrays, and one single-needle lead (a "4-4-4-1" harness configuration). An additional wire harness option was added for the NSS-2 BRIDGE with 4 percutaneous leads: three single-needle leads, and one 4-needle array (a "1-1-1-4" harness configuration).

3. The NSS-2 BRIDGE kit includes sterile adhesive strips and a pen light.

4. The material of the PNFS plastic housing changed from (b) (4) is medical grade. Data is on file to support conformance to ISO 10993-1.

5. The NSS-2 BRIDGE includes the use of a transillumination technique to place the device.

## SUMMARY OF NONCLINICAL/BENCH STUDIES

New biocompatibility, electrical safety, electromagnetic compatibility, shelf life, sterility, and software testing was not required for the NSS-2 BRIDGE device as the device is nearly identical to the EAD device cleared in K140530. In the sections below, the testing provided for the K140530 submission is summarized to support the safety and effectiveness of this device for its intended use (see the 510(k) Summary for K140530 for more information). The technological changes detailed above do not impact any results of the testing. Additional information on these changes and why they do not impact the results of the testing are discussed in the associated sections below.

### BIOCOMPATIBILITY/MATERIALS

Biocompatibility information for DEN170018 was leveraged from data previously provided for the EAD device cleared under K140530.

**Table 2: List of Patient-Contacting Materials**

| Patient Contacting Device Component | Nature of Tissue Contact | Duration of Tissue Contact |
|---|---|---|
| Tweezers | No skin contact | No skin contact |
| Transilluminator (pen light) | Behind ear | < 1 minute<br>Material biocompatibility data provided. |
| Kitted Bag containing Fixation Plasters | Over needle arrays on front surface of ear | Up to 120 hours<br>Material biocompatibility data provided. |
| Surgical Marker | On front surface of ear | Up to 120 hours<br>Material biocompatibility data provided. |
| Multi-pin wire harness percutaneous electrode array | Implanted percutaneously on front surface of ear | Up to 120 hours<br>Materials used in the needle arrays are identical to the materials used in the 510(k)-cleared EAD (K140530). |
| Foam Adhesives | Behind ear | Up to 120 hours<br>Foam adhesive material is identical to the materials used in the 510(k)-cleared EAD (K140530) |

Several changes were made in the NSS-2 BRIDGE device in comparison to the previously cleared device in K140530:

1. The EAD wire harness array has 4 leads: three 4-needle arrays and one single-needle lead. The NSS-2 BRIDGE additional wire harness has 4 leads: one 4-needle array, and three single-needle leads.
2. A pen light is included in the NSS-2 BRIDGE kit.
3. The material for the EAD housing is (b) (4) The material of the PNFS signal generator housing is (b) (4)

The tweezers, transilluminator (pen light), alcohol swab, and surgical marker are Class I, 510(k)-exempt products packaged as part of the convenience kit.

The fixation plasters and foam adhesive were tested for cytotoxicity, sensitization, and irritation in K140530 per FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. All results demonstrated acceptable performance.

The medical grade titanium of the percutaneous electrode arrays that comes into contact with the patient is identical to the medical grade titanium of the previously cleared percutaneous electrodes (K140530) in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents). Though the needle array configuration was changed for the NSS-2 BRIDGE device, this change does not impact the biocompatibility of the needles and no additional testing was requested.

The material of the PNFS generator's plastic housing changed from (b) (4) which may adversely impact the biocompatibility of the device. However, the plastic housing is not patient contacting because 510(k)-cleared foam adhesive is used to prevent transient contact of the housing with the patient.

**SHELF LIFE/STERILITY**

Shelf life and sterility information was largely leveraged from information previously provided for the EAD device cleared under K140530 because there have been no changes to the sterilization method, shelf life, or packaging with the NSS-2 BRIDGE, which has an additional wire harness option with 4 percutaneous leads: three single-needle leads, and one 4-needle array (a "1-1-1-4" harness configuration).

Sterilization Validation was conducted on the wire harness percutaneous electrode arrays using the using the VDMAX25 method according to ISO 11137-2:2007 "Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose" and demonstrated that a sterility assurance level (SAL) of $10^{-6}$ was accomplished with (b) (4) kGy. The device fulfilled the requirements of sterility according to ISO 11737-2:2009 "Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization

process."

The master packaging for the device is comprised of three parts:

1. The main tray is a vacuum formed single piece of plastic approximately 12 inches in length and 8 inched wide. The depth of the packaging is ¾ of an inch. There are five vacuum formed compartments that house the internal components in a secure fashion.

2. The cover for the packaging is clear sheet of film that is heat-sealed to ensure proper closure and protection of vital components.

3. The sterile sub-pack that houses the wire harness and needle array assembly. It is a 4 ½ x 1 inch vacuum formed enclosure consisting of a top and bottom that is then vacuum sealed inside a plastic medical grade bag.

The performance and stability of the device's packaging system during sterilization, distribution and labeled shelf life (b) (4) were validated in accordance with ISO 11607-1:2009, using accelerated-aged device samples. Accelerated aging of the device was performed according to ASTM F1980-07:2011. Validation was based on packaging material qualification, according to ISO 11607-1:2009, and the machine qualifications of the sealing processes, according to ISO 11607-2:2006.

## ELECTROMAGNETIC COMPATIBILITY (EMC) AND ELECTRICAL SAFETY

Electrical safety and EMC information was leveraged from information previously provided for the EAD device cleared under K140530 because there were no changes to the electrical components of the device. The only change associated with electrical safety is an alteration to the duty cycle of the NSS-2 BRIDGE from (b) (4) 120 hour run-time.

The device conformed to the following electromagnetic compatibility, electrical, mechanical, and thermal safety standards:

- IEC 60601-1 - Medical Electrical Equipment; Part 1: General Requirements for Basic Safety and Essential Performance.

- IEC 60601-1-2 - Medical Electrical Equipment; Part 1-2: General Requirements for Safety – Section 2: Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

- IEC 60601-2-10 - Medical Electrical Equipment; Part 2-10: Particular Requirements for the Safety of Nerve and Muscle Stimulators.

## SOFTWARE

Software information was leveraged from information previously provided for the EAD

device cleared under K140530 because there were no major changes to the electrical components or software of the device. Software verification and validation testing were conducted and documentation was provided in K140530 as recommended in FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," issued May 11, 2005. The software for this device was considered a "Minor" level of concern.

The only change associated with software and electrical safety is an alteration to the duty cycle of the NSS-2 BRIDGE (b) (4) 120 hour run-time. Additional software verification was successfully performed for the NSS-2 BRIDGE device to verify that the new output duty cycle performed as specified.

**PERFORMANCE TESTING – BENCH**

Additional electrical bench testing was leveraged from information previously provided for the EAD device cleared under K140530. The following tests were performed under a 1kΩ resistance to validate that the electrical performance met the specifications of the device:

- Verification of the temporal characteristics and amplitude of the pulse train through the leads and percutaneous electrodes
- Verification of the pulse train duty cycle
- Verification that the device does not exceed the maximum operating time of 120 hours

Additional verification was successfully performed for the NSS-2 BRIDGE device to verify that the new output duty cycle and pulse characteristics performed as specified.

**SUMMARY OF CLINICAL INFORMATION**

A single-arm, open label, multi-center retrospective study was done that included 73 patients (ranging from 18-65 years old; mean age = 32.9 ± 9.4) who met DSM-IV criteria (the classification found in the Diagnostic and Statistical Manual of Mental Disorders, 4th edition, published by American Psychiatric Association) for opioid dependence and voluntarily presented to outpatient drug treatment clinics between June 2015 and July 2016. Inclusion criteria included being 18 years of age or older, having a positive urine toxicology screen for opioids, and having a Clinical Opioid Withdrawal Score (COWS) of 5 or greater. Participating clinics located across five states provided data from patients treated with the NSS-2 BRIDGE: St. Louis, MO (27), Liberty, IN (13), Florence, KY (12), Anchorage, AK (9), Rising Sun, IN (6), Richmond, IN (2), Dayton, OH (2), and Indianapolis, IN (2). The participating treatment centers provided individualized evaluation, stabilization, and treatment. Variations exist among the eight outpatient clinics in terms of patient base, with an approximate daily census ranging from 4 to 25 patients.

As part of the treatment protocol in using the NSS-2 BRIDGE device, initial Clinical Opioid Withdrawal Scale (COWS) scores were recorded at baseline and at three other time intervals (20, 30 and 60 minutes) after the start of treatment in all patients. The COWS measures opioid withdrawal symptoms using 11 criteria and scores range from 0-48. As part of the protocol to evaluate the NSS-2 BRIDGE device, scores are rated as mild (5-12), moderate (13-24), moderately severe (25-36), or severe (>36). Note that as stated above, patients were required to have a COWS score of 5 or greater in order to be included in this retrospective study. These scores were extracted from the medical chart. COWS scores were also extracted as recorded in the medical chart at 5 days post BRIDGE placement when available.

The use of any rescue medications during the first hour of neurostimulation with the NSS-2 BRIDGE, including anti-psychotics, narcotics or benzodiazepines was monitored. However, no rescue medications were utilized within the first 60 minutes of NSS-2 BRIDGE use. Patients were instructed to follow-up within 1-5 days, depending on the clinic, and to leave the device on for the entire 5 day period. Patients were also instructed to return the device once removed so that it could be properly disposed. The protocol required monitoring of any adverse events associated with the device during the study. However, no adverse events were observed during the study.

Basic descriptive statistics were used for participant demographics. Non-parametric analysis with repeated measures ANOVA was used to evaluate effectiveness in reducing withdrawal scores across all time periods measured. Missing COWS scores were encountered at 20 min (11/73) and at 60 min (2/73). Imputing of missing data was not performed and analysis was made only with available data since the missing values were considered missing at random. Data were presented as mean (±standard deviation) and $p<0.05$ was considered statistically significant.

In the 73 subjects, the mean age was 32.9 (±9.4) years old and 65% were male. The mean length of drug use was 70 (±55) months and 90.5% of the subjects had been using opioids for at least 2 years. Immediately prior to BRIDGE placement, the majority of patients in this study, 53/73 (72.6%) fell into the moderate withdrawal range, while 16/73 (21.9%) were in the moderately severe range and 4/73 (±5.4 %) were in the mild range. Table 3 provides information about patient's baseline information.

| **Table 3: Patient Demographics and Drug Use Characteristics** | |
|---|---|
| **Age** in years **(SD)** | 32.9 (9.4) |
| **Gender (%)** | |
| Male | 48 (65) |
| Female | 25 (35) |
| **Duration of Drug Use in Months (SD)** | 70 (55) |
| **Opioids Used (%)** | |
| Heroin | 50 (68) |
| Prescription Narcotics | 23 (31) |
| Buprenorphine/naloxone | 24 (33) |
| Methadone | 7 (9) |

| **Presence of Poly-drug Use (%)** | |
|---|---|
| Marijuana | 15 (21) |
| Benzodiazepines | 13 (18) |
| Cocaine | 2 (.03) |
| Alcohol | 0 (0) |

All patients who received the NSS-2 BRIDGE device were enrolled in the study. In this group of patients (n=73), the mean COWS score prior to NSS-2 BRIDGE placement was 20.1 (±6.1). Twenty minutes after NSS-2 BRIDGE placement, the mean score was reduced by 62.7% to 7.5 (±5.9) ($p<0.001$ vs baseline scores).

The mean score continued to decrease after 30 minutes to 4.0 (±4.4) and 60 minutes to 3.1 (±3.4) (84.6% reduction, $p<0.001$ vs baseline scores). No rescue medications were used during this period. On day 5, a total of 64 patients returned to the clinic for medically assisted therapy (MAT) demonstrating a successful MAT transition for 88.8% of the patients (64/73). Of these 64 patients, the COWS score was only recorded for thirty-three (33) patients. The mean withdrawal score for this subset of 33 patients on day 5 was 0.6 (97.1% reduction, $p<0.001$ vs baseline scores). All patients who transitioned to MAT had a negative urine toxicology screen for opioids prior to administering the MAT. Overall, 73/73 (100%) subjects had a reduction in COWS scores by 30 minutes with a minimum decrease of at least 31%. The results are shown in Figure 6.

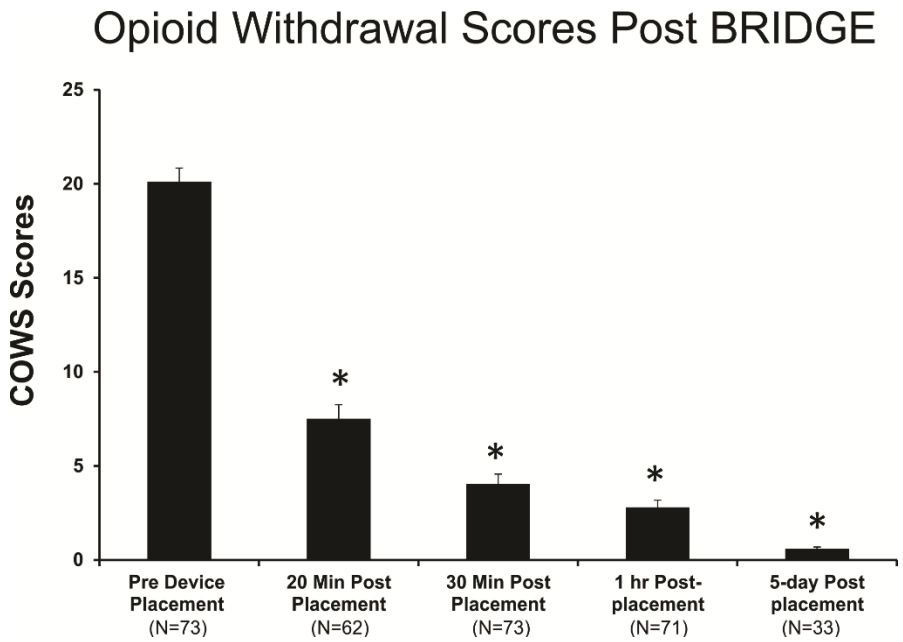


**Figure 6. Opioid withdrawal scores before and after NSS-2 BRIDGE device placement. A significant decrease in the clinical opioid withdrawal scale (COWS) scores was seen after applications of the device at all time points measured (*$p<0.001$ vs baseline scores). Results are based on a total number of 73 patients who received the NSS-2 BRIDGE device.**

At 60 minutes 57/73 (78.0%) had withdrawal scores of ≤ 3. During the entire 5 day period, no anti-psychotic, narcotic or benzodiazepine medications were given. Thirty eight percent (28/73) of patients received an antiemetic.

*Safety analysis*

No adverse events were recorded in any subject during the entire time of neurostimulation with the NSS-2 BRIDGE. Percutaneous therapies, generally, have risks of bleeding or infection at the puncture site, or skin irritation or pain at the site of application.

A separate study was performed to quantify percutaneous nerve field stimulator (PNFS) safety. In the retrospective chart review of the placement of 1207 PNFS devices including the NSS-2 BRIDGE (19312 punctures) across 6 US sites for a variety of indications, there were the following adverse events: bleeding (n=11), pain (n=2), dermatitis (n=11). All events were resolved spontaneously following removal of the device (Roberts A, Sithole A, Sedghi M, Walker CA, Quinn TM. Minimal adverse effects profile following implantation of periauricular percutaneous electrical nerve field stimulators: a retrospective cohort study. *Medical Devices (Auckland, NZ)*. 2016;9:389-393. doi:10.2147/MDER.S107426). This study only reported safety data and did not include effectiveness data.

*Pediatric Extrapolation*

In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population under 18 years of age.

## LABELING

Labeling for the NSS-2 BRIDGE resembles labeling previously provided for the EAD device cleared under K140530. The NSS-2 BRIDGE Instructions for Use are consistent with the clinical data and cover all the hazards and other clinically relevant information that may impact use of the device. The labeling includes the following contraindications:

- *Use of cardiac pacemakers because no clinical data is available;*
- *Hemophilia;*
- *Psoriasis vulgaris;*

and clarifies that *an intact skin surface is essential for the use of NSS-2 BRIDGE stimulator.* A summary of the clinical data used to support the proposed intended use is provided including a description of the risks and adverse events associated with normal use of the NSS-2 BRIDGE device. The labeling provides adequate instructions for use to inform the health care provider in the correct placement and safe use of the NSS-2 BRIDGE including information on the shelf life and technical parameters of the device. The labeling satisfies the requirements of 21 CFR § 801.109.

## RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of a percutaneous nerve stimulator for substance use disorders and the measures necessary to mitigate these risks.

**Table 4: Identified Risks to Health and Mitigation Measures**

| Identified Risk | Mitigation Measures |
|---|---|
| Adverse tissue reaction | Biocompatibility evaluation<br>Labeling |
| Electrical, mechanical, or thermal hazards leading to user discomfort or injury | Electromagnetic compatibility testing<br>Electrical, mechanical, and thermal safety testing<br>Non-clinical performance testing<br>Software verification, validation and hazard analysis<br>Labeling |
| Infection | Sterility testing<br>Shelf life testing<br>Labeling |

**SPECIAL CONTROLS:**

In combination with the general controls of the FD&C Act, the percutaneous nerve stimulator for substance use disorders is subject to the following special controls:

1. The patient-contacting components of the device must be demonstrated to be biocompatible.

2. Electromagnetic compatibility and electrical, mechanical, and thermal safety testing must be performed.

3. Electrical performance testing of the device and electrodes must be conducted to validate the specified electrical output and duration of stimulation of the device.

4. Software verification, validation, and hazard analysis must be performed.

5. Sterility testing of the percutaneous components of the device must be performed.

6. Shelf life testing must be performed to demonstrate continued sterility, package integrity, and device functionality over the specified shelf life.

7. Labeling must include the following:
    a. A detailed summary of the device technical parameters;
    b. A warning stating that the device is only for use on clean, intact skin;
    c. Instructions for use, including placement of the device on the patient; and
    d. A shelf life.

## BENEFIT/RISK DETERMINATION

The risks of the device are based on nonclinical laboratory data as well as data collected in a clinical study described above.

No adverse events were noted in the study of opioid withdrawal (n=73).

In the retrospective chart review of 1207 patients receiving PNFS devices including the NSS-2 BRIDGE (this represents 19312 punctures) across 6 US sites for a variety of indications, the following adverse events were observed: bleeding (n=11), pain (n=2), dermatitis (n=11). All events resolved spontaneously following removal of the device (Roberts A, Sithole A, Sedghi M, Walker CA, Quinn TM.; 'Minimal adverse effects profile following implantation of periauricular percutaneous electrical nerve field stimulators: a retrospective cohort study'. *Medical Devices (Auckland, NZ)*. 2016;9:389-393. doi:10.2147/MDER.S107426.). Percutaneous therapies, generally, have risks of bleeding or infection at the puncture site, or skin irritation or pain at the site of application. No infections have been noted in the use of this device.

The probable benefits of the device are also based on data collected in a clinical study as described above.

This study demonstrated that individuals who received the NSS-2 BRIDGE device had a clinical benefit as shown by a change in the COWS of, on average, greater than 15%. A COWS score change of 15% for a given individual is considered clinically significant (Wesson and Ling 2003, Tompkins et al 2009). Twenty minutes after NSS-2 placement, there was a mean 62.7% reduction in the COWS. At 60 minutes into the treatment of withdrawal with this device, there was a mean 84.6% reduction in the COWS. The risks are minimal, limited, and rarely occur. Even though individual level analyses are not available, the results indicate that the benefits compared to the risks are favorable.

Additional factors to be considered in determining probable risks and benefits for the NSS-2 BRIDGE include:

- The study used to support this indication was a single-arm, open label, multi-center retrospective study. The lack of controls increases the uncertainty of the placebo effect.

- Variations exist amongst the eight outpatient clinics with an approximate daily patient volume ranging from 4 to 25. Because the clinics varied in terms of patient volume, the standard of care in addition to the use of this device may also have varied in undetermined ways.

- It is not clear if any other inclusion or exclusion criteria, for example, medical history or concomitant medicine were also used to select subjects who were treated in these eight clinics. It is also not clear how many patients were screened initially from the eight clinics and, among those who were screened, how many failed to meet enrollment criteria.

- The study did not include a long-term evaluation of safety and effectiveness or information on repeated use.

- Day 5 COWS scores were not recorded for 40/73 subjects, however 64/73 (88.8%) successfully transitioned to medically assisted therapy (MAT). All patients who transitioned to MAT had a negative urine toxicology screen for opioids prior to administering the MAT. The effects of opioid withdrawal typically dissipate by Day 5 with or without the use of the subject device.

While factoring these considerations into our decision, the clinical results, especially at one hour, suggest a probable benefit of the device.

References

Tompkins DA, Bigelow GE, Harrison JA, Johnson RE, Fudala PJ, Strain EC. Concurrent Validation of the Clinical Opiate Withdrawal Scale (COWS) and Single-Item Indices against the Clinical Institute Narcotic Assessment (CINA) Opioid Withdrawal Instrument. *Drug and alcohol dependence*. 2009;105(1-2):154-159.

Wesson DR, Ling W. The Clinical Opioid Withdrawal Scale. J Psychoactive Drugs. 2003 Apr-Jun;35(2):253-9.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, the data support use as an aid to reduce the symptoms of opioid withdrawal, through application to branches of Cranial Nerves V, VII, IX and X, and the occipital nerves identified by transillumination. The probable benefits outweigh the probable risks for the NSS-2 BRIDGE. The device provides substantial benefits and the risks can be mitigated by the use of general and the identified special controls.

## CONCLUSION

The De Novo request for the NSS-2 BRIDGE is granted and the device is classified under the following:

Product Code: PZR
Device Type: Percutaneous nerve stimulator for substance use disorders
Class: II
Regulation: 21 CFR 882.5896