August 28, 2024

Bistos Co., Ltd.
Goeun Choi
Regulatory Affairs Staff
7th Fl., A Bldg., Woolim Lions Valley 5-Cha, 302
Galmachi-Ro, Jungwon-Gu, Seongnam
Gyeonggi, 13201
Korea, South

Re: K232991
Trade/Device Name: Bt-1000
Regulation Number: 21 CFR 882.5898
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Attention Deficit Hyperactivity Disorder
Regulatory Class: Class II
Product Code: QGL
Dated: July 5, 2024
Received: July 29, 2024

Dear Goeun Choi:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Doe W. Kumsa -S

Pamela D. Scott
Assistant Director
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K232991

Device Name
BT-1000

Indications for Use *(Describe)*
The BT-1000 external Trigeminal Nerve Stimulation System is indicated for treatment of pediatric Attention Deficit Hyperactivity Disorder (ADHD) as a monotherapy in patients ages 7 through 12 years old who are not currently taking prescription ADHD medications. The device is to be used for patient treatment by prescription only and is intended to be used in the home under the supervision of a caregiver during periods of sleep.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary

[As required by 21 CFR 807.92]

## 1. Date Prepared [21 CFR 807.92(a)(a)]

July 5, 2024

## 2. Submitter's Information & Contact Person [21 CFR 807.92(a)(1)]

- Name of Manufacturer: BISTOS Co., Ltd.
- Address: 7th Fl. A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea (Zip. 13201)
- Contact Name: Goeun Choi / RA Staff
- Telephone No.: +82-(0)31-750-0340
- Fax No.: +82-(0)31-750-0344
- Email Address: gechoi@bistos.co.kr

## 3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

- Trade name: BT-1000
- Common name: Transcutaneous electrical nerve stimulator for Attention Deficit Hyperactive Disorder

| Classification Description | 21 CFR Section | Product Code |
|---|---|---|
| Transcutaneous Nerve Stimulator For Adhd | 882.5898 | QGL |

As stated in 21 CFR parts 882.5898 of devices has been classified as Class II.

## 4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate device within this submission are shown as follows:

Predicate device

- De Novo Number: DEN180041
- Applicant: NeuroSigma, Inc.
- Classification Name: Transcutaneous nerve stimulator for adhd
- Trade Name: Monarch eTNS System

## 5. Description of the Device [21 CFR 807.92(a)(4)]

Electrical stimulator that alleviate the symptoms of Attention Deficit Hyperactivity Disorder (ADHD), a psychological mental disorder, by non-invasively stimulating cranial nerves with fine electrical stimulation using extracorporeal electrodes.
The treatment protocol using the BT-1000 is administered each night while the patient is sleeping, for 7-9 hours. The device is designed to provide non-invasive electrical stimulation of the trigeminal nerve via an electrode placed on the forehead. The trigeminal nerve is the largest cranial nerve and has three major sensory divisions of the face, all of which are bilateral.
The trigeminal nerve provides a direct connection to multiple brain structures implicated in ADHD and other neurologic and neuropsychiatric disorders.

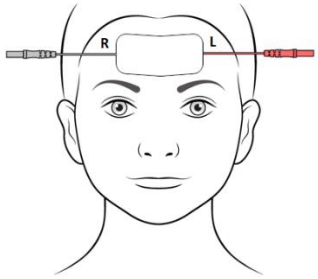
## 6. Indications for Use [21 CFR 807.92(a)(5)]

The BT-1000 external Trigeminal Nerve Stimulation System is indicated for treatment of pediatric Attention Deficit Hyperactivity Disorder (ADHD) as a monotherapy in patients ages 7 through 12 years old who are not currently taking prescription ADHD medications.
The device is to be used for patient treatment by prescription only and is intended to be used in the home under the supervision of a caregiver during periods of sleep.

## 7. Determination of Substantial Equivalence [21 CFR 807.92(a)(6) and 21 CFR 807.92(b)]

The identified predicate device within this submission are shown in the following table:

| | Proposed Device | Predicate Device | SE decision |
|---|---|---|---|
| 510(k)/ Denovo Number | K232991 | DEN180041 | - |
| Manufacturer | Bistos Co., Ltd | NeuroSigma, Inc. | - |
| Trade/ Device Name | BT-1000 | Monarch eTNS System | |
| Intended Use | Transcutaneous electrical nerve stimulator for Attention Deficit Hyperactivity Disorder. | Monarch eTNS System is Transcutaneous electrical nerve stimulator for Attention Deficit Hyperactivity Disorder. | Same |
| Definition | A transcutaneous electrical nerve stimulator for Attention Deficit Hyperactivity Disorder (ADHD) is a prescription device that stimulates transcutaneously or percutaneously through electrodes placed on the forehead. | A transcutaneous electrical nerve stimulator for Attention Deficit Hyperactivity Disorder (ADHD) is a prescription device that stimulates transcutaneously or percutaneously through electrodes placed on the forehead. | Same |
| Review Panel | Neurology | Neurology | Same |
| Physical State | Electrical stimulation unit with leads and cutaneous electrodes. | Electrical stimulation unit with leads and cutaneous electrodes. | Same |
| Technical Method | Applies an electrical current through electrodes on patient's skin. | Applies an electrical current through electrodes on patient's skin. | Same |
| Target Area | Trigeminal nerve | Trigeminal nerve | Same |
| Indications for Use | The BT-1000 external Trigeminal Nerve Stimulation System is indicated for treatment of pediatric Attention Deficit Hyperactivity Disorder (ADHD) as a monotherapy in patients ages 7 through 12 years old who are not currently taking prescription ADHD medications.<br>The device is to be used for patient treatment by prescription only and is intended to be used in the home under the supervision of a caregiver during periods of sleep. | The Monarch external Trigeminal Nerve Stimulation (eTNS) System is indicated for treatment of pediatric Attention Deficit Hyperactivity Disorder (ADHD) as a monotherapy in patients ages 7 through 12 years old who are not currently taking prescription ADHD medications.<br>The device is to be used for patient treatment by prescription only and is intended to be used in the home under the supervision of a caregiver during periods of sleep. | Same |

| Picture |  |  | Similar |
|---|---|---|---|
| Power Source | Rechargeable battery | Rechargeable battery | Same |
| S/W provided | Basic Documentation Level | MODERATE level of concern | Same |
| Max output current | 10mA | 10mA | Same |
| Patient Override Control Method | On/Off button | On/Off button | Same |
| Max Leakage Current | None (battery operated) | None (battery operated) | Same |
| Indicator display: Unit functioning | Yes | Yes | Same |
| Low battery indicator | Yes | Yes | Same |
| Timer Setting | Yes | Yes | Same |
| Expected Service Life(Device) | 5 years | 5 years | Same |
| Electrical Protection | Type BF | Type BF | Same |
| Battery Type | Lithium ion Battery | Lithium ion Battery | Same |
| Expected Service Life(Battery) | 300 cycles of complete charge-discharge | 300 charges per battery<br>(10 months each) | Same |
| Device housing materials | Plastic ABS | Plastic ABS | Same |

| | | | |
|---|---|---|---|
| Net Charge per pulse | 2.5 uC (Max 10 mA) | 2.5 uC | Same |
| Peak and peak-to-peak current Peak voltage | ± 10 mA | ± 10 mA | Same |
| Phase duration | 250 us | 250 us | Same |
| Maximum average power density | 7.5 mW/cm^2 | 7.5 mW/cm^2 | Same |
| Maximum current density | 1.4 mA/cm^2 | 1.4 mA.cm^2 | Same |
| Stimulating Surface Area of the Electrode | 7.1 cm^2 | 7.1 cm^2 | Same |
| And include the stimulation modulation specifications (Ramp up, Ramp down, on, and off and times for ramp up, ramp down, on, and off. | 30 Sec ON, 1 Sec Ramp Down / 30 sec OFF, 1 Sec Ramp Up Steady 7-9 hours | 30 Sec ON: 1 Sec Ramp Down: 30 Sec OFF: 1 Sec Ramp Up Steady 7-9 hours | Same |

Comparison between Subject and Predicate Device

1) Similarities

The subject device has the same indications for use as the predicate device. It also has the same performance parameters, such as physical state, technical method, stimulating surface area of the electrode, and the same technical specifications, such as maximum output current, net charge per pulse, and maximum current density, indicator, expected service life(battery), battery type, electrical protection, and etc. Regarding the technical specification about electric power and current, please refer to performance testing result.

The requirements for the Basic Documentation Level presented in the FDA Guidance "Content of Premarket Submissions for Device Software Functions" are equivalent to the MODERATE level of

concern in the previous obsolete Guidance. Therefore, the Software Documentation Level of the subject device is considered to be the same as that claimed in the Predicate Device.

2) Discussion

Based on the similarities between the subject device and the predicate device, the subject device is substantially equivalent to the predicate device. And, safety and biocompatibility testing confirmed that the subject device was producing the intended performance advocated by the subject device. Therefore, BT-1000 is considered to be substantially equivalent to the predicate device and can be safely marketed.

## 8. Non-Clinical Test Summary [21 CFR 807.92(b)(1)]

1) Biocompatibility Test

The electrode has limited duration (<24 hours) with intact skin. Therefore, per the FDA guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1 : Evaluation and testing within a risk management process", and ISO 10993-1 : Biological Evaluation of Medical Devices – Part 1 : Evaluation and Testing, Cytotoxicity, Sensitization, and Irritation testing were performed for the electrode. The following table summarizes the tests performed and the results :

| Test Title | Test Standard | Test Result | Date of Issue | Test Report |
|---|---|---|---|---|
| In Vitro Cytotoxicity Test | ISO 10993-5:2009 | Cytotoxic grade 1 | 24 May 2024 | AD-G2248 |
| Irritation Test | ISO 10993-23:2021 | Non-irritant | 27 October 2023 | AD-G1721 |
| Skin sensitization Test | ISO 10993-10:2021 | Non-sensitizer | 27 October 2023 | AD-G1722 |

2) Electrical Safety and Electromagnetic Compatibility Testing
Bench tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards;

| No. | Standard Identifier | Standard Title |
|---|---|---|
| 1 | IEC 60601-1: 2005+A1:2012+A2:2020 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| 2 | IEC 60601-1-2: 2014+A1:2020 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance |

| | | |
|---|---|---|
| 4 | IEC 60601-1-11: 2015+A1:2020 | Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance |
| 5 | IEC 60601-2-10 : 2012/AMD2:2023 | Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators |

3) Performance Testing – bench
The following tests were performed to assess effectiveness of performance of the device.

| No. | Test Item | Description | Report. No. |
|---|---|---|---|
| 1 | Stimulation output Waveform Testing | To confirm the simulation output using an oscilloscope to demonstrate that the device can produce its intended stimulation parameters | RDD-2311-0001 |
| 2 | Battery performance testing | To confirm the operating time and charging time of the battery | RDD-2402-0008 |
| 3 | Stimulation duration testing | To confirm that it operates for the set duration | RDD-2403-0002 |
| 4 | Stimulation signal output testing | To confirm the accuracy and measurement accuracy of stimulation electrical output. | RDD-2403-0005 |
| 5 | Electrode testing | To confirm that adhesive integrity, visual, dimension, impedance and packing integrity of the electrode met specifications for the duration of its shelf life. | TR-BSTS-240308 |
| 6 | Stimulation signal output of electrode testing | To confirm that the electrical performance of electrodes met specifications for the duration of its shelf life. | RDD-2403-0003 |

4) Software Validation
The BT-1000 contains Basic documentation level. The software was designed and developed according to a software development process and was verified and validated. The software information is provided in accordance with FDA guidance: “Content of Premarket Submissions for Device Software Functions, on June 14, 2023” and “ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices”.

| No. | Test Items | Standards and FDA Guidance Documents |
|---|---|---|
| 1 | General requirement for safety – Programmable electrical medical systems (PEMS) | - IEC 62304:2006/AMD1:2015<br>- FDA Guidance (Content of Premarket Submissions for Device Software Functions) |

## 9. Clinical Test Summary [21 CFR 807.92(b)(2)]

No clinical studies were considered necessary and performed.

## 10. Conclusion [21 CFR 807.92(b)(3)]

The subject device and the predicate device are substantially equivalent in terms of general information, performance parameters, and technical specifications. Although there are some differences, the safety and performance test reports support the safety and effectiveness of the subject device. In this regard, we conclude that the subject device is substantially equivalent to the predicate device.