July 9, 2022

Pourang Bral, DDS, LLC
President
155 Albion Street
Passaic, New Jersey 07055

Re: K220573
Trade/Device Name: Noodle
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Dated: February 15, 2022
Received: February 28, 2022

Dear Dr. Bral:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Pamela 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)*
K220573

Device Name
Noodle

Indications for Use *(Describe)*
Noodle is intended to reduce the pain of hypodermic injections into the upper extremities (arms), lower extremities (leg), buttocks, abdomen, and deltoid areas in patients 18 to 70 years of age.

The Noodle device may be used in the home by patients who self-administer injections or in a medical setting by professional healthcare providers.

Body parts intended to be conditioned by the Noodle device are sites that are commonly the target of injections such as the upper and lower extremities (arms and legs), buttocks, abdomen, and deltoid and is not intended to be used on smaller body parts such as the hands, feet, head (including ears, nose and around the eyes), the neck, and the abdominal area in pregnant women.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Type of submission: Traditional 510(k)

Date: July 9, 2022
Submitter: Pourang Bral, DDS, LLC
Address 155 Albion Street, Passaic, NJ 07055 Phone: 201 264-4862
Contact: Pourang Bral
Email: Pourangb@gmail.com

Identification of the Subject Device

Device name	Noodle
Common or usual name	Electrical and mechanical stimulator for injection site pain reduction
Classification product code	NUH
Device classification	II
Regulation number	882.5890
Regulation description	Transcutaneous electrical nerve stimulator for pain relief.
Review panel	Neurology

This is an application for a 510K approval of a device called Noodle that uses electrical and physical stimulation on the skin to temporarily anesthetize an injection site prior to an injection to reduce the pain of the injection without the use of chemicals.
Noodle is a battery-operated handheld device that includes a TENS unit and a motor operated by a 9V commercial battery. The classification product code for Noodle is NUH. Noodle is a Class II Device: § 882.5890 - Transcutaneous electrical nerve stimulator for pain relief. Once it is activated, it operates for 25 seconds and shuts off automatically.

Identification of the predicate device

Predicate Device K130802

Device name	OTC Electrical Stimulator LT3060
Common or usual name	Transcutaneous Electrical Nerve Stimulator
Classification product code	NUH, NGX
Device classification	II

Regulation number	21 CFR 882.5890
Regulation description	Transcutaneous Electrical Nerve Stimulator for Pain Relief
Review panel	Neurology

The predicate device is the OTC Electrical Stimulator LT3060, with the stated indication for use of Temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. It has a 510(K) number of K130802, a Product Code NUH, and a Classification Name of Stimulator, Nerve, Transcutaneous, over the counter.

Indications for use of the subject device

Noodle is intended to reduce injection-site pain of hypodermic injections into the upper extremities (arms), lower extremities (leg), buttocks, abdomen, and deltoid areas in patients 18 to 70 years of age.

The Noodle device may be used in the home by patients who self-administer injections or in a medical setting by professional healthcare providers.

Body parts intended to be conditioned by the Noodle device are sites that are commonly the target of injections such as the upper and lower extremities (arms and legs), buttocks, abdomen, and deltoid and is not intended to be used on smaller body parts such as the hands, feet, head (including ears, nose and around the eyes), the neck, and the abdominal area in pregnant women.

Description of the Device

Noodle consists of a TENS unit and a small motor that causes a polyurethane sponge stick to rotate and tap the skin. The combination of the TENS application and tapping on the skin for 25 seconds numbs the skin temporarily for a subsequent injection. The sponge stick is impregnated in 70% isopropanol and disinfects the injection site at the same time it taps it.

The device body has 5 pieces, the enclosure, the button, the bottom, the battery door, and the receptacle. Noodle further includes a PCB that is controlled by a firmware. The PCB supplies TENS stimulation that is transferred to the skin by a pair of hydrogels that come in electrical contact with the skin around the injection site.

Statement of Conformity

List of FDA recognized voluntary consensus standards cited in this submission.

IEC 60601-1
IEC 60601-1-2
IEC 60601-2-10

IEC 60601-1-11

Discussion of non-clinical tests

i. ANSI AAMI ES60601-1: 2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD)

ii. ANSI AAMI IEC 60601-1-2:2014, Medical Electrical Equipment -- Part 1-2: General Requirements for Basic Safety and Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements and Test

iii. IEC 60601-2-10 Edition 2.1 2016-04, Medical Electrical Equipment - Part 2-10: Particular Requirements for The Basic Safety and Essential Performance of Nerve and Muscle Stimulators

iv. IEC 60601-1-11 Edition 2.0 2015-01, Medical Electrical Equipment - Part 1-11: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment (General II (ES/EMC))

Noodle has passed all these non-clinical tests.

Discussion of clinical tests

The clinical performance data supporting the safety and effectiveness of the Noodle device for reducing the pain of hypodermic injections into the extremities, buttocks, abdomen, and deltoid (as described in the Indications for Use statement) was based on a multi-site sham-controlled double-blind causal-comparative trial using the Noodle device in 18 patients at 3 sites (one doctor's office and two pharmacies). The sham device was identical to the Noodle but did not deliver stimulation.

The 18 patients were divided into two groups: 9 who received treatment with the Noodle device first and 9 getting the sham first. Each subject gave themselves two needle sticks. Prior to each needle stick, they preconditioned the needle stick site either by the Noodle or a sham. The VAS pain scale was used to assess the level of pain. The sponsor assessed the improvement in acute pain from baseline before the needlestick to after, in comparison to the sham using two metrics: the peak pain score (peak VAS) and average pain score (average VAS).

77% of subjects (14 of 18) reported a reduction in pain scores of at least 3 or greater on the VAS scale, about 30% pain reduction, when the injection site was preconditioned with Noodle. No adverse events were reported in the 18 subjects. Average VAS was lower with Noodle than with the sham device by 35%. The difference seen in the clinical results was considered to provide clinical benefit to patients given that a sham-controlled, double-blind trial and the study results did not indicate any significant adverse effects or safety risks for this device. Hence, the results were considered to provide clinical benefit in reducing the pain of hypodermic injections into the extremities, buttocks, abdomen, and deltoid.

Substantial Equivalence Determination

Both Noodle and the predicate device use TENS stimulation to achieve their desired effects.

A side-by-side comparison of the technological characteristics of Noodle and the cited predicate device is included in the table below.

	New Device	**Predicate Device**	**Substantial Equivalence Determination**
1. 510(k) Number		K130802	
2. Device Name, Model	Noodle	OTC Electrical Stimulator LT3060	
3. Manufacturer	Painless World	Shenzhen Dongdixin Technology Co. Ltd	
4. Power Source(s) Battery	(9V – user replaceable)	9V Battery	Same
- Method of Line Current Isolation	N/A	N/A	Same
- Patient Leakage Current	N/A		
- Normal condition	N/A	0.61uA	This parameter is not applicable to the new device.
- Single fault condition	N/A	0.68uA	This parameter is not applicable to the new device.
5. Number of Output Modes	1	1	Same
6. Number of Output Channels	1	Alternating	Different but does not adversely impact safety and effectiveness of the new device.
- Synchronous or Alternating?	N/A	Alternating	This parameter is not applicable to the new device.

- Method of Channel Isolation	N/A	By electrical circuit and software	This parameter is not applicable to the new device.
7. Regulated Current or Regulated Voltage?	Regulated Voltage	Regulated Current	Different but does not adversely impact safety and effectiveness of the new device.
8.Software/Firmware/ Microprocessor Control?	Yes	Yes	Same
9. Automatic Overload Trip?	Yes	Yes	Same
10. Automatic No-Load Trip?	No	Yes	Different but does not adversely impact safety and effectiveness of the new device.
11. Automatic Shut Off?	Yes	Yes	Same
12. Patient Override Control?	No	Yes	Different but does not adversely impact safety and effectiveness of the new device.
13. Indicator Display:			
- On/Off Status?	Yes	Yes	Same
- Low Battery?	No	Yes	Different but does not adversely impact safety and effectiveness of the new device.
- Voltage/Current Level?	Yes	Yes	Different but does not adversely impact safety and effectiveness of the new device.

14. Timer Range	25 seconds	1-60 minutes	New device is several times safer than the predicate because of the short usage time.
15. Compliance with Voluntary Standards? (If yes, specify)	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 ISO 10993-5/10	Different but does not adversely impact safety and effectiveness of the new device.
16. Compliance* with 21 CFR 898? Yes / No	Yes	Yes	Same
17. Weight	119 grams, including a 9V battery	128 grams (including batteries)	Different but does not adversely impact safety and effectiveness of the new device.
18. Dimensions (in.) [W x H x D]	120 x 45 x 47	117 x 60 x 34 mm	Different but does not adversely impact safety and effectiveness of the new device.
19. Housing Materials and Construction	Polypropylene	ABS	Different but does not adversely impact safety and effectiveness of the new device.
Waveform (e.g., pulsed monophasic, biphasic)	Monophasic	Biphasic	Different but does not adversely impact safety and effectiveness of the new device.

Shape (e.g., rectangular, spike, rectified sinusoidal)	Rectangular	Square	Different but does not adversely impact safety and effectiveness of the new device.

Maximum Output Voltage@ 500Ω	28.6V	96+-20% (48+-20% (Vp))	Different but does not adversely impact safety and effectiveness of the new device.
Maximum Output Voltage @ 2kΩ	94.3V	228+-20% (114+-20% (Vp))	Different but does not adversely impact safety and effectiveness of the new device.
Maximum Output Voltage @ 10kΩ	125.7V	230+-20% (115+-20% (Vp))	Different but does not adversely impact safety and effectiveness of the new device.
Maximum Output Current @ 500Ω	58mA	96+-20%	Different but does not adversely impact safety and effectiveness of the new device.
Maximum Output Current @ 2kΩ	50mA	57+-20%	Different but does not adversely impact safety and effectiveness of the new device.
Maximum Output Current @ 10kΩ	14mA	11.5 +-20%	Different but does not adversely impact safety and effectiveness of the new device.
Pulse Width	9us - 113us	50 - 300uS	Different but does not adversely impact safety and effectiveness of the new device.

Frequency	150Hz	1-150Hz	Different but does not adversely impact safety and effectiveness of the new device.
Net Charge (mC per pulse) @ 500Ω	7uC	0uC@500Ω	Different but does not adversely impact safety and effectiveness of the new device.
Maximum Phase Charge, (mC) @ 500Ω	7uC	0.0288@500Ω	Different but does not adversely impact safety and effectiveness of the new device.
Maximum Current Density, (mA/cm²) @ 500Ω	4.23mA/cm2	1.15@500Ω	Different but does not adversely impact safety and effectiveness of the new device.
Maximum Power Density, (mW/cm²) @ 500Ω	120mW/cm2	Unavailable	
Max. Average Power Density, mW/cm² (using smaller electrode conductive surface area	2.03	0.373@500Ω	

The electronic characteristics listed in the table above were designed to be equivalent to those of the predicate. They were then measured and confirmed in the lab. The power source in Noodle and predicate are the same. In lines 5 and 6, the output modes and output channels in the predicate are more numerous. The predicate offers more output modes, and the user opts for one of them. Noodle offers only one output mode and one output channel that are offered by the predicate.

In line 14, the time range for Noodle is significantly less than the predicate.
Similarly in lines 15 and 16, the predicate offers more choices in waveform and in pulse width range than Noodle. Noodle is preset to offer only one of those options offered by the predicate. Line 22 shows what the Noodle enclosure is made of. This material meets all applicable industrial standards.

Conclusion

All nonclinical tests recommended by the FDA were performed and found Noodle to meet all the requirements of the stated standards. In addition, Noodle was tested clinically and was shown to effectively and safely reduce pain of hypodermic injections into the upper extremities (arms), lower extremities (leg), buttocks, abdomen, and deltoid areas in patients 18 to 70 years of age.