FDA News Release

FDA grants marketing authorization of the first device for use in helping to reduce the symptoms of opioid withdrawal

For Immediate Release

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Summary

FDA permits marketing of the first device for use in helping to reduce the symptoms of opioid withdrawal

Release

Today, the U.S. Food and Drug Administration granted a new indication to an electric stimulation device for use in helping to reduce the symptoms of opioid withdrawal.

“Given the scope of the epidemic of opioid addiction, we need to find innovative new ways to help those currently addicted live lives of sobriety with the assistance of medically assisted treatment. There are three approved drugs for helping treat opioid addiction. While we continue to pursue better medicines for the treatment of opioid use disorder, we also need to look to devices that can assist in this therapy,” said FDA Commissioner Scott Gottlieb, M.D. “The FDA is committed to supporting the development of novel treatments, both drugs and devices, that can be used to address opioid dependence or addiction, as well as new, non-addictive treatments for pain that can serve as alternatives to opioids.”

The NSS-2 Bridge device is a small electrical nerve stimulator placed behind the patient’s ear. It contains a battery-powered chip that emits electrical pulses to stimulate branches of certain cranial nerves. Such stimulations may provide relief from opioid withdrawal symptoms. Patients can use the device for up to five days during the acute physical withdrawal phase. Opioid withdrawal causes acute physical withdrawal symptoms including sweating, gastrointestinal upset, agitation, insomnia and joint pain.

To permit marketing of this device for this use, the FDA reviewed data from a single-arm clinical study of 73 patients undergoing opioid physical withdrawal. The study evaluated patients’ clinical opiate withdrawal scale **(COWS) score (https://www.drugabuse.gov/sites/default/files/files/ClinicalOpiateWithdrawalScale.pdf)**, which is a clinical assessment conducted by a health care professional that measures opioid withdrawal symptoms such as resting pulse rate, sweating, pupil size, gastrointestinal issues, bone and joint aches, tremors and anxiety. COWS scores range from 0 to more than 36 — the higher the number, the more severe the withdrawal symptoms are to a patient.

Prior to using the device, the average COWS score for all patients was 20.1. Study results showed that all patients had a reduction in COWS of at least 31 percent within 30 minutes of using the device. Overall, 64 of the 73 patients (88 percent) transitioned to medication assisted therapy after five days using the device, along with any medications needed for persistent symptoms, such as nausea and vomiting.

The FDA cleared the **EAD (https://www.accessdata.fda.gov/cdrh_docs/pdf14/K140530.pdf)**(electro auricular device, now called Bridge Neurostimulation System) in 2014 for use in acupuncture. FDA's granting of the current request for the NSS-2 Bridge expands the use of the device as an aid to reduce the symptoms of opioid withdrawal. It is available only by prescription. The device is contraindicated for patients with hemophilia, patients with cardiac pacemakers or those diagnosed with psoriasis vulgaris.

The FDA reviewed the NSS-2 Bridge device through the de novo premarket review pathway, a regulatory pathway for some low- to moderate-risk devices that are novel and for which there is no legally marketed predicate device to which the device can claim substantial equivalence.

The FDA permitted marketing of the NSS-2 Bridge device to Innovative Health Solutions, Inc.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information

- **FDA: Recently Approved Devices (https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/default.htm)**
- **FDA: De Novo Pathway (/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm462775.htm)**
- **FDA: Bridge Neurostimulation System (https://www.accessdata.fda.gov/cdrh_docs/pdf17/DEN170018.pdf)**
- **FDA: Opioid Medications (/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm)**
- **NIDA: Opioid Addiction (https://www.drugabuse.gov/drugs-abuse/opioids)**

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