FDA NEWS RELEASE

FDA permits marketing of first medical device for relief of pain associated with irritable bowel syndrome in patients 11-18 years of age

For Immediate Release:

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The U.S. Food and Drug Administration today permitted marketing of the first medical device to aid in the reduction of functional abdominal pain in patients 11-18 years of age with irritable bowel syndrome (IBS) when combined with other therapies for IBS. IBS is a condition affecting the large intestines that can cause abdominal pain and discomfort typically related to bowel movements.

“This device offers a safe option for treatment of adolescents experiencing pain from IBS through the use of mild nerve stimulation,” said Carlos Peña, Ph.D., director of the Office of Neurological and Physical Medicine Devices in the FDA’s Center for Devices and Radiological Health. “Today’s action reflects our ongoing commitment to advancing the development of pediatric medical devices so that children and adolescents have access to safe and effective medical devices that meet their needs.”

The IB-Stim is a prescription-only device comprised of a small single-use electrical nerve stimulator that is placed behind the patient’s ear. It contains a battery-powered chip that emits low-frequency electrical pulses to stimulate branches of certain cranial nerves continuously for five days, at which time it is replaced. Stimulating nerve bundles in and around the ear is thought to provide pain relief. Patients can use the device for up to three consecutive weeks to reduce functional abdominal pain associated with IBS.

IBS is a group of symptoms that occur together, including repeated pain in the abdomen and changes in bowel movements, which may be diarrhea, constipation or both. With IBS, the symptoms can be present without any visible signs of damage or disease in the digestive tract.

The FDA reviewed data from a published clinical study that included 50 patients 11-18 years of age with IBS - 27 patients were treated with the device and 23 patients received a placebo device. The study measured change from baseline to the end of the third week in worst abdominal pain, usual pain and Pain Frequency Severity Duration (PFSD) scores, which incorporate multiple aspects of pain experience. Changes in bowel movements were not evaluated. During the study, patients were allowed to continue stable doses of medication to treat chronic abdominal pain.

Worst pain at baseline was similar between the treatment and placebo groups. A repeated measures analysis showed a greater change (improvement) in worst pain from baseline to week three in the treatment group. This effect was also seen at weeks one and two. Greater change was also demonstrated in composite PFSD scores from baseline to week three in the IB-Stim group compared to the placebo group. IB-Stim treatment resulted in at least a 30% decrease in usual pain at the end of three weeks in 52% of treated patients compared to 30% of patients who received the placebo, and at least a 30% decrease in worst pain in 59% of treated patients compared with 26% of patients who received the placebo. During the study, six patients reported mild ear discomfort and three patients reported adhesive allergy at the site of application.

The device is contraindicated for patients with hemophilia, patients with cardiac pacemakers or those diagnosed with psoriasis vulgaris (a condition in which skin cells build up and form scales and itchy, dry patches).

The FDA reviewed the IB-Stim through the de novo premarket review pathway, a regulatory pathway for low- to moderate-risk devices of a new type. This action creates a new regulatory classification, which means that subsequent devices of the same type with the same intended use may go through the FDA's 510(k) premarket process, whereby devices can obtain marketing authorization by demonstrating substantial equivalence to a predicate device.

Similar versions of this device for other uses were previously granted marketing authorization by the FDA. The NSS-2 BRIDGE (/news-events/press-announcements/fda-grants-marketing-authorization-first-device-use-helping-reduce-symptoms-opioid-withdrawal) was permitted for marketing in 2017 as an aid to reduce the symptoms of opioid withdrawal. The FDA first cleared a version of the device, known as the Electro Auricular Device (https://www.accessdata.fda.gov/cdrh_docs/pdf14/K140530.pdf), in 2014 for use in acupuncture.

The FDA granted marketing authorization of the IB-Stim to Innovative Health Solutions.

The FDA, an agency within the U.S. Department of Health and Human Services, promotes and protects the public health by, among other things, assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency is also 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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