

**TIVIC HEALTH RECEIVES FDA 510(k) CLEARANCE
TO MARKET CLEARUP™ TO TREAT SINUS PAIN
ASSOCIATED WITH ALLERGIC RHINITIS/HAY FEVER**

SAN FRANCISCO, CA, JANUARY 3, 2019 - [Tivic Health Systems](#) Inc. today announced that ClearUP Sinus Pain Relief, a first-in-class bioelectronic treatment for sinus pain due to allergic rhinitis (hay fever), has received 510(k) clearance from the U.S. Food and Drug Administration (FDA). ClearUP is an over-the-counter (OTC) device that provides consumers with a simple, non-invasive and drug-free option to relieve sinus pain caused by various environmental allergies such as dust, mold, pollens and pet dander.

ClearUP uses gentle microcurrent waveforms to provide sinus pain relief to the 40 to 60 million Americans who suffer from allergic rhinitis. Its state-of-the-art technology measures the user's unique skin properties to target the optimal treatment points. A small, handheld device, ClearUP easily glides along the outside of the nasal passages -- the cheek, nose and brow bone -- to deliver low current electrical waveforms that stimulate the nerves under the skin to help relieve sinus pain. ClearUP will be available over-the-counter without a prescription by mid-2019.

As part of its FDA submission, Tivic Health conducted a double-blind, randomized control trial with 71 patients with sinus pain, to evaluate the effect of microcurrent waveforms on sinus pain. In this pivotal trial, it was demonstrated that after one treatment with ClearUP, three out of four users achieved sinus pain relief (74 percent). In addition, 82 percent of those who used ClearUP preferred it over their current treatment(s). The results of this trial, conducted in May 2018 at a top-tier U.S. research science center, were presented at the American Rhinologic Society Annual Meeting in October 2018.

"In line with our corporate vision to create accessible, cutting-edge solutions for chronic conditions, we are very pleased to bring to market a next generation microcurrent device that will help transform treatment for the common allergy sufferer," said Jennifer Ernst, CEO of Tivic Health. "ClearUP's FDA clearance marks a major milestone for Tivic Health and puts us on the map as an innovative leader in the field of bioelectronics and neuromodulation."

"For the many patients suffering from allergy-related sinus pain, we now have an effective treatment option that does not involve pills, a spray or nasal flush, surgery or opioids. ClearUP is an important new option that is drug-free, side-effect free and non-invasive," added Subinoy Das, MD, FACS, FARS, Chief Executive Officer and Medical Director for the U.S. Institute for Advanced Sinus Care and Research; and a member of Tivic Health's Medical Advisory Board.

Sinus sufferers are concerned about taking sinus medicine and its side effects. The company's earlier third-party research with 600 sinus pain sufferers revealed that 95 percent wanted to decrease the amount of medicines they were taking and 91 percent were concerned about side effects from their current treatments.

ClearUP's one-button control is easy-to-use and offers three intensity levels to personalize treatment to best suit the needs of the individual. ClearUP is intended for adults only, 18+ years of age, and can be used whenever needed, up to four times a day. Each treatment session takes five minutes. ClearUP is reusable and rechargeable, and can be used at work, home or while traveling.

About Bioelectronic Technology

Bioelectronics, a \$6.2 billion industry, combines biology and electrical engineering. Devices work by modulating electrical activity in peripheral and central nerves to mitigate symptoms and/or underlying causes of disease. It is being studied to treat a range of diseases including rheumatoid arthritis, drug resistant epilepsy and alcoholism. The most common bioelectronics device is the pacemaker, first introduced in 1958. In September 2018, bioelectronics was named as one of the top ten disruptive technologies by the World Economic Forum.

About Tivic Health Systems Inc.

Tivic Health Systems Inc. (Tivic Health™) is a bioelectronic device company dedicated to developing microcurrent therapy solutions for chronic diseases and conditions. Tivic Health's first product, ClearUP™ Sinus Pain Relief, targets sinus pain associated with allergic rhinitis. Founded in 2016, Tivic Health is part of a \$6.2B global neuromodulation industry. The team is dedicated to harnessing the power of neuromodulation for home use products, empowering people to improve their health and quality of life. For more information, visit www.tivichealth.com and follow us on Twitter at @TivicHealth and on Facebook at www.facebook.com/TivicHealth.

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FDA Press Release