

FDA EXPANDS INDICATION FOR USE OF TIVIC HEALTH'S CLEARUP SINUS PAIN RELIEF TO INCLUDE CONGESTION FOR COMMON COLD, FLU AND ALLERGIES

Helping Millions Through Bioelectronics Without Medication

SAN FRANCISCO, March 24, 2021 - [Tivic Health® Systems Inc.](#), a first-in-class developer of bioelectronics health devices, today announced that the U.S. Food and Drug Administration (FDA) has expanded the indication for use of ClearUP® Sinus Pain Relief to include congestion from allergies, the flu, and the common cold. This is in addition to FDA clearance for treating allergy-related sinus pain caused by seasonal and year-round allergies.

Available at major online retailers nationwide, ClearUP now provides consumers with congestion relief without the use of medication. A small handheld device, ClearUP is a non-invasive and drug-free treatment that uses gentle microcurrent to relieve sinus and nasal congestion and allergy-related sinus pain.

As part of its FDA De Novo Request grant, Tivic Health's clinical studies showed that ClearUP was effective in treating moderate to severe congestion. Study subjects with moderate to severe congestion reported on average 35% reduction in congestion symptoms 10 minutes after a ClearUP treatment and this was significantly greater than placebo. After four weeks of regular use, subjects reported an average 44% reduction in congestion symptoms.

"We are at the tip of the iceberg in developing novel bioelectronic device applications to treat chronic conditions without medication. Of particular note, this FDA De Novo Request grant breaks new ground as it creates an area of technology never before granted by the FDA -- microcurrent for congestion relief. We are proud to be the first and look forward to reaching millions without drugs or chemicals," said Jennifer Ernst, CEO of Tivic Health. "As the bioelectronics industry continues to invest in both basic science and clinical research, these devices will become more effective and will tackle all types of inflammatory clinical conditions."

"Bioelectronic devices stimulate the body to produce factors that it very tightly regulates. In the case of ClearUP, it stimulates the trigeminal nerve, which is responsible for sensing pain and pressure of the face, and also sympathetic fibers of the autonomic nervous system, which can induce vasoconstriction and reduced swelling. Together, modulation of

these pathways provides rapid relief of sinus pain and congestion without the side effects that often come with drugs used for these symptoms. For the large number of patients affected by sinus pain and congestion, whether from allergies or infections, this is a game-changing new product,” said Subinoy Das, MD, chief medical officer at Tivic Health and CEO and Medical Director, U.S. Institute for Advanced Sinus Care and Research.

ClearUP® Sinus Pain Relief Milestones

In September 2020, the U.S. Patent and Trademark Office issued four patents for ClearUP that cover the device, its interface and a number of features that allow it to be comfortable, effective and ergonomic. The patents address device specifications, comfort features, device performance during treatment, and future product development. The company has an additional 14 patents pending in the U.S and abroad.

Last spring ClearUP received CE Mark approval for temporary relief of sinus pain, pressure and congestion, under the brand name ClearUP Sinus Relief. The combination of the Company’s FDA Clearance and CE Mark approval opens the market for ClearUP to sell in over 190 countries.

How ClearUP Works

ClearUP uses gentle microcurrent waveforms to provide sinus pain and congestion relief to the [50 million allergy sufferers](#) in the US. 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 and congestion. ClearUP is available over the counter without a prescription at Amazon, Best Buy, Sharper Image, Walgreens, Walmart, among others.

About Tivic Health Systems Inc.

Founded in 2016, Tivic Health is part of a \$6.2B global bioelectronics industry that is dedicated to harnessing the power of neuromodulation for home use products that treat chronic diseases and conditions that empower people to improve their health and quality of life. ClearUP has received awards from: [Last Gadget Standing CES 2020](#), [Digital Trends Best Health Gadgets CES 2020](#), [TIME’s 2019 Best Inventions](#) and [CES 2020 Innovation Honoree Award](#). @TivicHealth

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