

FDA Grants U.S. Clearance to Market Wearable Ultrasound Therapy Device

ZetrOZ Inc.

First non-invasive ultrasound device cleared by the FDA for sustained drug-free pain therapy

[ZetrOZ Inc.](#) [1] today



announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for the marketing of its ultrasound pain management device [sam](#) [1], a wearable, long-duration, ultrasonic diathermy device for use in applying deep therapeutic treatment. In line with current clinical needs, sam, available by prescription, can be used to treat musculoskeletal and joint pain in adults. Clinical studies backing this technology demonstrate a measurable, drug-free decrease in pain via a wearable, non-invasive therapeutic patch.

sam is the first and only long duration continuous ultrasound therapy product that is FDA cleared for relief of pain, relief of muscle spasm, treatment of joint stiffness and increased local circulation.

“The device uses high-frequency ultrasonic excitations to produce deep mechanical stimulation within the body, increasing circulation, reducing inflammation and pushing nutrients through the body’s cellular structures,” attests product inventor and company co-founder, George K. Lewis, Jr., Ph.D. who adds, “sam is clinically proven to be an effective deep therapeutic treatment for select medical conditions and, when used daily provides added therapeutic benefit for chronic pain patients.”

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The rechargeable sam ultrasound therapy device can be worn daily for up to four hours on a single charge, providing continuous relief of pain or used as part of a rehabilitation program to increase local circulation of injured tissues for multiple hours. sam can be prescribed and administered by a clinician or physical therapist, alone, or in tandem with other treatments. The leadership team behind sam, who were awarded a [National Institutes of Health \(NIH\)](#) [2] grant of \$397,000 to support clinical trials on knee osteoarthritis pain for the technology, plans to launch the device by spring of 2014.

“The use of therapeutic ultrasound to treat a variety of conditions, including musculoskeletal pain, offers great promise to our patients,” says [Thomas M Best MD, PhD](#) [3], Professor and Pomerene Chair, Division of Sports Medicine, Ohio State University. “In particular, this low intensity, iPod-sized, wearable, battery powered device and its early success in a series of pilot studies represent a breakthrough in our abilities to treat patients in a user friendly, convenient manner.”

“Sixty-seven percent of those over 40 live with aches and pains,” continued Dr. Lewis, who recently conducted a [national survey on pain management](#) [4]. “sam has been proven to significantly reduce pain without the use of pharmaceuticals and could be the next generation of wearable tech to make a ‘quality of life’ breakthrough for millions of chronic pain sufferers. Furthermore, the science around sam, and the usefulness of miniature devices that provide long-duration therapeutic ultrasound, hold significant promise in the field of bioelectronic medicine.”

sam is available by prescription from licensed healthcare practitioners such as primary care, orthopedists, rheumatologists, pain specialists and physiotherapists in the United States. In Europe and Canada, sam is CE-marked and licensed, respectively, and available over-the-counter directly to the patient.

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Links:

[1] <http://www.samrecover.com/>

[2] <http://finance.yahoo.com/news/zetroz-inc-awarded-397-000-175005155.html>

[3] http://sportsmedicine.osu.edu/ourteam/physicians/thomas_best/

[4] <http://www.marketwired.com/press-release/majority-of-baby-boomers-live-with-pain-but-remaining-active-is-a-priority-1871052.htm>