FDA Grants 510(k) Market Clearance for Whole Body Postoperative Pain to World Leader in Low Level Laser Technology

Randomized and controlled peer reviewed published clinical trials on 635 nm red laser prove effectiveness for treatment

As the World Leader in Low Level Laser Technology, we have always believed we need to continue expanding the science of this amazing technology. This latest U.S. FDA 510(k) statement adds to our commitment.

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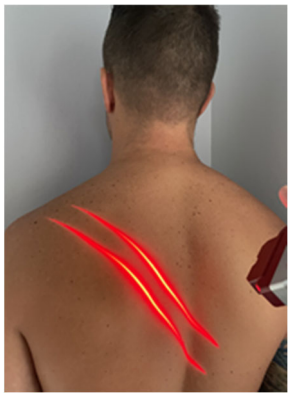

Erchonia, the World Leader in Low Level laser Technology announces that on October 22, 2021, they have received their latest 510(k) statement from the U.S. FDA based on level 1 blinded and controlled clinical trials. 510(k) #211186

The new FDA 510(k) statement for whole body treatment of postoperative pain was based on the company's previously granted 510(k) statements from 2004 and 2008 along with data from seven randomized clinical trials on coronary artery bypass graft surgery, coronary bypass surgery with internal mammary artery grafts, tibial fracture surgery, cesarean section, endodontic surgery and tonsillectomy.

This groundbreaking FDA market clearance provides a drug free & safe treatment option for postoperative pain. Based on clinical data, subjects who received Erchonia laser treatments experienced approximately 50% less pain and consumed less narcotics than the placebo group. The relief in subjects' pain was reduced immediately after surgery & extended through 1 week, 2 week & 1 month post operation. These blinded and controlled clinical trials have once again proven the Erchonia lasers as superior to light emitting diodes (LEDs) which were used as a placebo device in each of the four measured time frames

There are estimated 234 million major surgeries performed globally each year. The Global Postoperative Pain Management Market was valued at USD 30 Billion in 2018 and is projected to reach USD 45 Billion by 2026. As the opioid crisis escalates, hospitals and physicians are increasingly seeking alternative ways to help patients manage pain throughout their hospital stay and beyond.

Travis Sammons, Erchonia's Clinical Affairs Manager stated, "The latest 510(k) statement once again proves Erchonia's commitment to the science of low-level laser therapy through blinded and controlled clinical trials to obtain FDA 510(k) marketing statements. As the World Leader in Low Level Laser Technology, we have always believed we need to continue expanding the science of this amazing technology. This latest US FDA 510(k) statement adds to our commitment".

About Erchonia
Erchonia created the low-level laser category (NHN) in January 2002 when we received the first ever FDA 510(k) marketing statement based on (2) level 1 clinical trials. Since that time, Erchonia has obtained over 20 different 510(k) statements from the U.S. FDA based on level 1 blinded and controlled clinical trials. These 510(k) marketing statements from the U.S. FDA are too numerous to list one by one. The 510(k) statements include a wide variety of medical conditions, from whole body chronic pain, whole body fat reduction, obesity and onychomycosis to the latest whole body postoperative pain. Erchonia currently has several new clinical trials in process and continues to further the science of low-level laser technology.