FDA Approves Multi Radiance Medical's Laser Technology for Pain Relief

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Jenna Payesko
@Jenna_Pay

The US Food and Drug Administration (FDA) recently cleared Multi Radiance Medical's MR4 Laser technology for neck and shoulder pain relief under the Product Classification NHN.

The approval was based on the results of a randomized study that demonstrated the effectiveness versus the placebo for reducing neck and shoulder pain.

The new NHN product class FDA 510(k) clearance provides clinicians and patients a clinically proven safe and effective alternative — a drug-free way for managing common pain.

According to the FDA, a product classified as NHN is defined as a LASER (Light Amplification by Stimulated Emission of Radiation) based device with coherence, collimated and typically monochromatic radiation.

The device emits energy in the infrared or other wavelengths providing a non-heating and non-thermal effect to be used in pain therapy or a related indication that does not provide therapeutic topical heating.

Even though therapeutic laser companies sell products in the US, only a select number receive clearance under the NHN designation, indicating a non-thermal device.

"The reason for this is the very rigorous and expensive process, which includes conducting and submitting data to support the claims of safety and effectiveness," Max Kanarsky, chief executive officer, Multi Radiance, said in a statement.

Multi Radiance Super Pulsed Lasers use innovative technology delivering light energy to tissue, reducing pain and increasing circulation. The lasers combine clinically proven wavelengths to create the energy effect, allowing for deeper penetration and enhanced absorption of light.

With the technology, super pulses can occur up to 50,000mW of power, which is more than most class IV lasers, yet with higher degrees of safety. The high power creates a high photon density to strongly reduce pain and improve microcirculation.

In the study, researchers aimed to investigate the effects of phototherapy in combination of different light sources on nonspecific knee pain in 86 patients that rated 30 or greater on the pain visual analogue scale (VAS).

Patients of the phototherapy with low-level laser therapy (LLLT) group received 12 treatments with active phototherapy (with 905 nm super-pulsed laser and 875 and 650 mm LEDS manufactured by Multi Radiance Medical) and conventional treatment, physical therapy or chiropractic care. Those in the placebo group were treated in the same way except with a placebo phototherapy device.

Pain assessments were performed at baseline and after treatments 4, 7 and 10, after the completion of treatments, and at the 1-month follow-up visit.

The findings concluded that phototherapy significantly decreased pain from treatment 10 to follow-up assessments and significantly improved SF-36 physical component summary at posttreatments and follow-up.

Overall, researchers from the study concluded that combination of super-pulsed laser, red and infrared light-emitting diode (LEDs) is effective to decreased pain, improving quality of life in patients with knee pain.