

Neurolyser XR Now FDA Cleared for Sale in USA.

Revolutionary Non-invasive Needleless Procedure for Treating Low Back Pain

ALPHARETTA, GA, UNITED STATES, November 17, 2025 /EINPresswire.com/ -- [FUSMobile](#), Inc. is proud to announce that it received De Novo marketing authorization (DEN250015) clearance from the FDA to begin marketing and sales of the Neurolyser XR system for the non-invasive treatment of low back pain.

The Neurolyser XR is a first-of-its-kind device that uses high-intensity focused ultrasound (HIFU) to non-invasively ablate sensory nerves innervating the facet joints—structures that are a leading source of chronic low back pain affecting millions of adults. Prior to the introduction of Neurolyser XR, standard treatments were limited to opioid medications, spinal injections, or invasive procedures.

“The adoption of focused ultrasound is accelerating globally, and we believe FUSMobile is poised to become the new standard of care across multiple clinical areas.”, said Dr. Arik Hananel, co-founder of FUSMobile, FUSMobile has spent the past eleven years developing the Neurolyser XR system. The device is currently:

- FDA Cleared for USA.
- Licensed by Health Canada
- CE Marked for the EU in conformity with the Medical Device Regulation (EU) 2017/745
- Registered in the UK

We take pride in our regulatory approvals and continue to work diligently to advance the Neurolyser platform in other markets while seeking additional clinical indications. What was once the realm of science fiction is now a clinical reality,” said Ron Aginsky, President and co-



founder of FUSMobile. "With the introduction of the Neurolyser XR, FUSMobile provides interventional pain physicians an innovative HIFU device that until now was costly and available only to interventional radiologists and neurosurgeons," continued, Mr. Aginsky.

"If a condition can be treated non-invasively, it should be," said Dr. Hananel—a guiding principle that defines the company's mission.

About FUSMobile

Founded in 2014 by Dr. Arik Hananel and Ron Aginsky, FUSMobile is dedicated to developing non-invasive, high-precision therapies for the treatment of chronic pain. In response to the global rise in musculoskeletal conditions and the aging population, FUSMobile aims to transform pain care through innovative technology. Dr. Hananel, a pioneer in focused ultrasound and former Scientific and Medical Director at the Focused Ultrasound Foundation, envisioned the Neurolyser XR as a faster, safer alternative to conventional treatments.

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