Medical Necessity and Clinical Efficacy

FDA Designation:

- **Exclusive FDA Market Authorization**: IpsiHand stands alone as the first and only non-invasive brain-computer interface (BCI) therapy to obtain FDA market authorization. It is important to highlight that **there are no comparable therapeutic alternatives** in the market for its specific indication.

Clinical Efficacy and Safety:

- **Superior UEFM Outcomes**: The device remarkably outperforms standard care, achieving an average improvement of **7.7 UEFM points** over 12 weeks. The minimal clinically important difference (MCID) for UEFM is +5.25, indicating significant clinical benefit.
- **Durable and Retained Gains**: Functional improvements extend to the hand, wrist, and arm, and are retained post-therapy, signifying durable, long-term benefits.
- **Zero Adverse Events**: Clinical studies report **no patient injury or adverse events**, solidifying its safety profile.

Mechanism of Action and Neuroplasticity

- **Proprietary Prosthetic Motor Circuit**: IpsiHand employs a unique prosthetic motor circuit, corroborated by functional MRI and electrophysiological studies, that effectively remodels the brain.
- **Reset in Phase Amplitude Coupling**: The therapy induces significant changes in phase amplitude coupling between theta and gamma rhythms, directly correlating with motor recovery.

Patient Population and Home-Based Therapy

- **Addresses Underserved Population**: Indicated for **chronic stroke patients (≥ 6 months post-stroke) aged 18 or older**, it serves an often-neglected demographic with limited therapeutic options.
- **Self-Administered Home Therapy**: IpsiHand offers the convenience of self-administered, home-based therapy, requiring just one-hour modules five days per week.