FDA Structured Functional Claim

Device: Resona Health Vibe (PEMF Device)

Intended Use: Adjunctive support for individuals with symptoms of Post-Traumatic Stress Disorder (PTSD)

Structured Functional Claim

Device Function

The Resona Health Vibe is a pulsed electromagnetic field (PEMF) therapy device designed for personal wellness. It is worn around the neck or carried in a pocket and delivers low-level, non-invasive electromagnetic pulses intended to support relaxation, stress management, and emotional well-being.

Target Population

Adults experiencing symptoms of Post-Traumatic Stress Disorder (PTSD).

Intended Effect

When used as directed, the Resona Health Vibe device is intended to support a reduction in self-reported PTSD symptom severity, as measured by standardized assessment tools such as the PTSD Checklist for DSM-5 (PCL-5), and to promote improvements in related domains of well-being.

Summary of Clinical Evidence

Key Study Outcomes

- **Original Pilot Study (n=21):**
    - 92% of participants reported a reduction in PTSD symptoms after using the device 3–4 times per week.
    - 66% experienced a reduction in PCL-5 scores greater than 11 points, considered clinically and statistically significant.
    - Mean reduction in symptom scores was highly significant ($p = 0.000007$).
    - No adverse effects reported12.
- **Report Update (n=44):**

    - Statistically significant improvements observed across all wellness domains, including mental clarity, emotional balance, sleep quality, stress management, social behavior, and alertness.
    - Large effect sizes and p-values < 0.0001 in most domains.
    - No adverse events; high compliance and tolerability12.
- **Expanded Cohort (n=500):**
    - 98% of participants reported a reduction in PTSD symptoms following use of the device.
    - Significant improvements in PTSD symptoms and overall well-being were consistently observed.
    - No significant adverse events reported to date.

Directions for Use

- Wear the device around the neck or in a shirt pocket.
- Run the PTSD protocol (2 hours, 15 minutes) 3–4 times per week for 30 days.
- Maintain adequate hydration prior to each session.

Limitations

- The functional claim is based on open-label pilot studies and real-world use; most data are self-reported and not from randomized controlled trials.
- The device is not intended to diagnose, treat, cure, or prevent any disease.
- Results may not be generalizable; further controlled clinical trials are warranted.

Summary Table of Study Results

Study Parameter	**Original Pilot (n=21)**	**Report Update (n=44)**	**Expanded Cohort (n=500)**
Symptom Reduction (any)	92%	Significant improvements	98% reported reduction
Clinically Significant Change	66% (>11-point PCL-5)	Large effect sizes	Maintained
Statistical Significance	$p = 0.000007$	$p < 0.0001$ in all domains	Maintained
Adverse Effects	None reported	None reported	None reported

Disclaimer

This functional claim is structured for FDA general wellness device communication and is not intended as a disease treatment claim. The device is marketed as a low-risk general wellness product.

References:

Resona.News/PTSD-Study