

### COMMON MISCONCEPTION

Devices without "FDA Approved" status are less safe, experimental, or require specialized prescribing, particularly within the VA system.

### REGULATORY REALITY

Over 90% of FDA-regulated medical equipment, including the vast majority of hospital-grade devices, is FDA Cleared through the 510(k) pathway.

| Risk Level                                                                 | FDA Status                               | What It Means                                                                                                                                                                                                                     | Everyday Examples                                                                                                                                                                                                                    |
|----------------------------------------------------------------------------|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>CLASS I</b><br>(Lowest Risk)                                            | <b>Registered / Exempt</b>               | Minimal risk, no premarket review, just official registration.                                                                                                                                                                    |  Clinical supplies, bandages, tongue depressors.                                                                                                  |
| <b>CLASS II</b><br>(Moderate Risk)<br><br>The FDA clearance standard path. | <b>FDA CLEARED</b><br>(via 510k process) | Evaluated by FDA and proven "substantially equivalent" to a trusted predicate. The standard for most hospital and therapy equipment.                                                                                              |  Infusion pumps, advanced patient monitoring, imaging, red light therapy wraps, virtual reality, sTMS migraine devices, PEMF wearables, and more. |
| <b>CLASS III</b><br>(Highest Risk)                                         | <b>FDA APPROVED</b><br>(via PMA pathway) | High-risk devices that sustain or support human life, are implanted, or present a potential unreasonable risk of illness or injury. They require rigorous PMA (Premarket Approval) review with clinical data before market entry. |  Pacemakers and artificial heart valves, deep-brain stimulators, cochlear implants, and high-frequency ventilators.                             |



## INSIGHT: FDA STATUS IN VAMC OPERATIONS

- **Standardize your understanding:** Demanding Class III "FDA Approved" status for a Class II "FDA Cleared" device needlessly halts access to proven, compliant medical technologies.
- **VAMC Administrators:** Class II FDA Cleared status is the established required standard for the vast majority of essential medical equipment, including hospital beds, critical monitors, as well as red light therapy, sTMS migraine devices, virtual reality, PEMF, etc. Using these safe and compliant devices supports mission-critical patient care.