

NEUROCONTRARIAN #005

Research Reference Document

FDA Regulatory Language in Neurofeedback & EEG Biofeedback:

What "FDA Registered," "FDA Cleared," and "FDA Approved" Actually Mean — and Why the Distinction Matters for Practitioners, Clients, and the Field

SYMMETRY Neuro-Pathway Training | April 2026 | For Internal & Educational Use

PURPOSE OF THIS DOCUMENT

This reference document provides the factual, sourced foundation for NeuroContrarian Issue #005. It is not a legal opinion and does not constitute legal advice. It is intended for educational use by practitioners, program operators, and organizations working in or adjacent to the neurofeedback and EEG biofeedback field. All regulatory citations are drawn directly from publicly available federal law, FDA databases, and company websites as of April 2026.

Section 1: The Four Regulatory Terms — What They Actually Mean

The FDA regulates medical devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Devices are classified into one of three risk-based classes, and the required pathway to market differs by class. Understanding those pathways is the only way to understand what regulatory language actually means.

1.1 FDA Approved (Premarket Approval — PMA)

"FDA Approved" has a precise legal meaning. It refers exclusively to devices that have completed the Premarket Approval (PMA) process — the highest and most stringent form of FDA device review, reserved for Class III devices.

- Class III devices are defined as those that "support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential, unreasonable risk of illness or injury."

- Before approving a PMA, the FDA requires the sponsor to provide valid scientific evidence demonstrating reasonable assurances of safety and effectiveness — typically including independent clinical trials.
- Examples of PMA-approved devices include cardiac implants, cochlear implants, and deep brain stimulators.
- NO standard EEG biofeedback or neurofeedback device holds a PMA. None of these devices are "FDA approved" in the technical, legal sense of that phrase.

Primary source: [FDA — Premarket Approval \(PMA\) Overview](#) | Authority: 21 CFR Part 814; Section 515 of the FD&C Act

1.2 FDA Cleared (510(k) Premarket Notification)

"FDA Cleared" is the correct and legally precise term for most neurofeedback and EEG biofeedback devices that have gone through formal FDA review. A 510(k) submission demonstrates that a device is "substantially equivalent" to a legally marketed predicate device — meaning it has the same intended use and similar technological characteristics.

- The FDA issues a clearance letter when it finds substantial equivalence. This order "clears" the device for commercial distribution.
- "Cleared" does not mean "approved." The FDA explicitly states these are different standards. Cleared devices have not undergone the independent clinical trials required for PMA approval.
- The cleared intended use is binding. A device cleared for relaxation training cannot be marketed for diagnosing conditions, treating specific disorders, or uses beyond what the clearance letter specifies.
- Several neurofeedback systems have received 510(k) clearances under Product Code HCC, Regulation 21 CFR 882.5050 (Biofeedback Device).

Primary sources: [FDA — 510\(k\) Premarket Notification Overview](#) | [FDA — Medical Device Safety and the 510\(k\) Process](#)

1.3 FDA Registered (Establishment Registration & Device Listing)

"FDA Registered" is the most widely misused and misunderstood term in the neurofeedback field. Manufacturers and distributors of medical devices are required by law to register their establishment annually with the FDA. This registration is a mandatory business compliance filing — not a product review, endorsement, or quality designation.

- The FDA's own consumer guidance states explicitly: "When a facility registers its establishment and lists its devices, the resulting entry in the FDA's registration and listing database does NOT denote approval, clearance, or authorization of that facility or its medical devices."

- The FDA does not issue "FDA Registration Certificates." Firms that display such certificates to imply product review are considered to be misbranding their devices — a federal violation under the FD&C Act.
- Registration is required of virtually all medical device businesses operating in the U.S. A company can be FDA-registered while selling a device that has never been reviewed, cleared, or approved by the FDA.
- Using "FDA registered" as a quality, safety, or legitimacy credential in consumer-facing marketing is, at minimum, misleading and, in context-dependent cases, may constitute misbranding under federal law.

Primary source: [FDA — Are There 'FDA Registered' or 'FDA Certified' Medical Devices?](#) (FDA Consumer Information Page, last updated 2021)

1.4 510(k) Exempt

Some Class I and a narrow category of Class II devices are exempt from the premarket notification requirement. This means a manufacturer can market the device without submitting a 510(k) to the FDA first — but must still register their establishment, list the device, and comply with all other general controls.

- Under 21 CFR 882.5050(b), a biofeedback device is exempt from 510(k) requirements ONLY when it is a prescription, battery-powered device indicated solely for relaxation training and muscle reeducation.
- This exemption is narrow and conditional on the specific intended use. Any claim beyond relaxation training and muscle reeducation removes the device from the exemption category.
- "510(k) exempt" does not mean unregulated — it means exempt from one specific premarket submission requirement only.

Primary source: [eCFR — 21 CFR 882.5050 Biofeedback Device](#)

Section 2: Where EEG & Neurofeedback Devices Fall Under Federal Law

Neurofeedback and EEG biofeedback devices are regulated under 21 CFR Part 882 — Neurological Devices. Two regulations are especially relevant to most devices in clinical use:

REGULATION	DEVICE TYPE	CLASSIFICATION & PATHWAY
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21 CFR 882.5050	Biofeedback Device (incl. EEG neurofeedback) — Product Code HCC	Class II — 510(k) required OR 510(k) exempt if indicated only for relaxation/muscle re-education
21 CFR 882.1400	Electroencephalograph (clinical EEG recording) — Product Codes GWQ, OMB, OMC	Class II — 510(k) required; performance standards apply
21 CFR 882.1440	Neuropsychiatric Interpretive EEG Assessment Aid (qEEG diagnostic software)	Class II — 510(k) required with special controls; device design must include safeguards preventing stand-alone diagnostic use
21 CFR 882.1450	Brain Injury Adjunctive Interpretive EEG Assessment Aid	Class II — 510(k) required with special controls; for adjunct use only, not stand-alone diagnosis

2.1 The Official FDA Definition of a Biofeedback Device

The FDA's definition under 21 CFR 882.5050(a) is precise and consequential for all marketing and clinical claims:

21 CFR 882.5050(a) — Official Definition

"A biofeedback device is an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters."

Key implications of this definition for practice and marketing:

- The device provides feedback — it does not diagnose, interpret, or treat specific conditions.
- The device enables the patient to voluntarily control physiological parameters — it is a training tool, not a diagnostic instrument.
- Any claim that the device differentiates clinical conditions (ADHD vs. anxiety), detects pathology (TBI markers, addiction circuitry), or produces clinical interpretations of neuropsychiatric status goes beyond the definition and enters a different, higher-scrutiny regulatory category.

2.2 The Boundary That Cannot Be Crossed: Diagnostic vs. Feedback Use

The FDA classifies neuropsychiatric interpretive EEG assessment aids (21 CFR 882.1440) separately from biofeedback devices precisely because diagnostic interpretation of EEG data is a fundamentally different — and higher-risk — function than providing feedback for self-regulation.

- A device cleared as a biofeedback device (HCC, 882.5050) cannot legally be marketed for diagnostic interpretation of neuropsychiatric conditions without a separate clearance under 882.1440.
- The special controls for 882.1440 explicitly state: "The device design must include safeguards to prevent use of the device as a stand-alone diagnostic."
- Marketing qEEG data as capable of "differentiating ADHD from anxiety," "detecting TBI electrical scar tissue," or "mapping neural pathways associated with craving" constitutes diagnostic claims that exceed any existing biofeedback device clearance.

Primary sources: [eCFR — 21 CFR Part 882 \(Full Text\)](#) | [eCFR — 21 CFR 882.1440 Neuropsychiatric Interpretive EEG Assessment Aid](#)

Section 3: Real-World Cleared Devices — What FDA Clearance Actually Says

The following neurofeedback devices have received 510(k) clearances under 21 CFR 882.5050 (Biofeedback Device, Product Code HCC). Each clearance letter specifies the exact intended use — and that intended use defines the boundary of legal marketing claims.

3.1 BrainMaster 2E — 510(k) K990538 (Cleared May 1999)

Clearance Database Record:

accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K990538

Cleared intended use (verbatim from the 510(k)):

"The BrainMaster equipment is indicated for relaxation training using alpha EEG Biofeedback. In the protocol for relaxation, BrainMaster provides a visual and/or auditory signal that corresponds to the patient's increase in alpha activity as an indicator of achieving a state of relaxation. The equipment is approved for Prescription Use."

Classification: Biofeedback Device / Electroencephalograph with EEG Signal Spectrum Analyzer and Biofeedback Options | Regulatory Class: II | Product Code: HCC

3.2 EEGer4 / EEG Software LLC — 510(k) K122879 (Cleared January 2013)

Clearance Document (PDF): accessdata.fda.gov/cdrh_docs/pdf12/K122879.pdf

Cleared intended use (verbatim from the 510(k)):

"This device is to be used for general relaxation training when used with supported amplifier/encoders. Operators of this device are expected to be health care practitioners trained in neurofeedback or technicians trained in neurofeedback supervised by health care practitioners."

Note: EEGer4 has since served as the primary predicate device for multiple subsequent 510(k) submissions, including GrayMatters Health's Prism (K222101).

3.3 Prism / GrayMatters Health — 510(k) K222101 (Cleared March 2023)

Clearance Document (PDF): accessdata.fda.gov/cdrh_docs/pdf22/K222101.pdf

Cleared intended use: A Software as Medical Device (SaMD) prescribed for patients with PTSD as an adjunct to standard of care. Uses EEG input for neurofeedback sessions. This clearance is notable because it represents a neurofeedback software cleared for a specific clinical population — but critically, as an adjunct, not a stand-alone treatment or diagnostic tool. Primary predicate: EEGer4 (K122879).

Section 4: The FDA Enforcement Precedent — NeuroField Warning Letter

In February 2022, the FDA issued a formal Warning Letter to NeuroField, Inc. — a neurofeedback and pEMF device manufacturer — citing violations directly relevant to the regulatory language issues documented in this report.

Warning Letter (Full Text): [fda.gov — NeuroField, Inc. 621767 — 02/28/2022](https://www.fda.gov/oc/2022/02/28/warning-letter-neurofield-inc-621767)

4.1 Key Findings from the Warning Letter

NeuroField had registered its devices as biofeedback devices under 21 CFR 882.5050. The FDA's inspection found that website statements and device manuals described intended uses that exceeded the biofeedback classification, including:

- Stimulation-based treatment claims that placed the device outside the biofeedback classification entirely.
- EEG recording functions described in marketing that would require separate 510(k) clearance under 21 CFR 882.1400 (Electroencephalograph).
- The FDA explicitly stated that a device registered as a biofeedback device under 882.5050 is not permitted to claim intended uses beyond that classification — even if the manufacturer believes the device is capable of those functions.

FOUNDATIONAL REGULATORY PRINCIPLE — ESTABLISHED BY WARNING LETTER

Intended use drives classification, and classification drives the required regulatory pathway. Marketing or labeling a device for uses beyond its cleared or classified category renders the device "adulterated" and "misbranded" under the FD&C Act — regardless of the manufacturer's belief in the device's capabilities or the practitioner's clinical intentions.

Section 5: Three-Tier Case Study — How "FDA Registered" Travels Through the Field

The following documents a real-world chain of regulatory language misrepresentation, progressing from a device manufacturer to a service provider to a licensed clinical residential program serving vulnerable young adults. All claims documented below are drawn verbatim from each organization's publicly accessible website as of April 2026.

IMPORTANT DISCLOSURE

This section documents publicly available marketing language from company websites. It does not constitute a legal finding of wrongdoing. No assumption is made about the specific device equipment used by service providers or residential programs, as that information has not been independently verified. The analysis is limited strictly to the marketing language each organization uses publicly.

Tier 1 — BrainMaster Technologies (Device Manufacturer)

Source: brainmaster.com/about-brainmaster/ and brainmaster.com/kb-entry/brainmaster-us-fda-registration-information/

What BrainMaster gets right:

- Holds legitimate 510(k) clearances: K990538 (biofeedback, 882.5050) and K150498 (clinical EEG, 882.1400).
- Their dedicated FDA Knowledge Base page correctly references 510(k) numbers and notes the cleared intended use for relaxation training.
- Their FAQ page and neurofeedback devices page correctly use the phrase "FDA-cleared."

Where the language becomes problematic:

On the About Us page (brainmaster.com/about-brainmaster/), BrainMaster states:

Directly Quoted — About Us Page

"Our systems are FDA registered, not only for Neurofeedback but also for clinical EEG. More importantly, they are registered for our normalizing quantitative EEG software database."

- Problem: Uses "FDA registered" to describe 510(k) clearances — blurring the line the FDA explicitly draws between establishment registration (administrative filing) and 510(k) clearance (marketing review).
- Problem: Promotes uses including infra-slow training, neuromeditation, neurofeedback-informed hypnotherapy, and pEMF therapy — none of which are within the cleared intended use of relaxation training under 882.5050.
- Problem: LinkedIn company page lists "FDA Approved" as a specialty keyword — flatly incorrect for any 510(k)-cleared device.
- Problem: The Knowledge Base page attempts to extend the biofeedback clearance's reference to "spectral analysis" into clinical EEG territory for all devices, when only the Discovery holds separate clinical EEG clearance (K150498).

Tier 2 — Neurologics (Neurofeedback Service Provider)

Source: neurologics.com (homepage and FAQ page)

Neurologics uses "FDA-registered technology" as its primary legitimacy credential across multiple pages. Unlike BrainMaster, which at least acknowledges 510(k) numbers in some contexts, Neurologics makes no reference anywhere on its website to 510(k) clearance, cleared intended uses, or what "registered" actually means under federal law.

Directly Quoted — Neurologics.com Homepage & FAQ

Homepage hero banner: "FDA-registered technology. Assessment and optimization praised by Olympians, professional athletes, and world-renowned scientists."

Feature list: "Uses FDA Registered Technology" [listed as a selling point under Why Use Neurologics?]

FAQ — Answer to "Is it safe?": "Yes. One hundred percent. Neurologics uses FDA-registered technology."

- Problem 1: Uses "FDA-registered technology" directly as proof of safety — precisely what the FDA says registration does not confer.
- Problem 2: No mention of 510(k) clearance, cleared intended use, or the distinction between registration and review anywhere on the site.

- Problem 3: Programs marketed for TBI, dementia, ADHD, autism, addiction, and cognitive decline — none of which are within the cleared indication for any biofeedback device.
- Problem 4: The FAQ answer to a direct safety question cites "FDA-registered technology" as the primary evidence of safety — a direct and documented misuse of the registration concept per FDA guidance.

Tier 3 — Skyterra Young Adult (Licensed Clinical Residential Program, Brevard, NC)

Source: skyterrayera.com (homepage)

Skyterra Young Adult is a licensed residential therapeutic program for young adults ages 18–29 in the Blue Ridge Mountains of North Carolina. It has partnered with Neurologics to offer brain mapping services and uses Neurologics' marketing language — including "FDA-registered" — across its own website. This represents the third and most consequential tier: a licensed clinical program serving a vulnerable population.

Directly Quoted — Skyterra Young Adult Homepage (skyterrayera.com)

Hero headline: "Skyterra is the only Young Adult Gap Semester program combining FDA-registered Neurologics™ brain mapping with therapy, education and immersive lifestyle coaching."

Body copy: "Skyterra Young Adult has partnered with Neurologics to provide their FDA-registered quantitative EEG (qEEG) brain mapping that studies the brain in real time."

Diagnostic claim: "True ADHD vs. Anxiety: Is it an attention deficit, or is the brain so hyper-aroused by anxiety that it cannot pay attention? The brain map differentiates these distinct electrical patterns, preventing misdiagnosis and unnecessary medication."

Diagnostic claim: "The hidden concussion: Many young adults struggle with focus or mood regulation due to undiagnosed Traumatic Brain Injuries (TBI) from sports or childhood accidents. qEEG can detect the electrical 'scar tissue' that MRIs miss."

Diagnostic claim: "The negative circuit: For guests who find themselves caught in recurring behavior patterns, we can map the specific neural pathways associated with impulse control and craving, allowing us to target the physiological roots of relapse."

- Problem 1: Places "FDA-registered" in the hero headline as the primary legitimacy claim for the entire diagnostic model.
- Problem 2: The diagnostic claims — differentiating ADHD from anxiety, detecting TBI electrical markers, mapping addiction circuitry — are of a specificity and clinical gravity that no 510(k)-cleared biofeedback device is authorized to make.
- Problem 3: These claims are presented to families of young adults ages 18–29 struggling with serious conditions including TBI, ADHD, autism, and addiction — a vulnerable population making significant clinical and financial decisions.

- Problem 4: The "FDA-registered" framing is used to establish federal government legitimacy for claims that have no regulatory basis under existing device clearances.
- Problem 5: Licensed clinicians operating within a program making these claims risk their own licensing board scrutiny, independent of FDA enforcement, if they do not correct the regulatory misrepresentation to clients in the informed consent process.

Section 6: Why This Matters for Both Industries

6.1 The Therapeutic Industry

The mental health and therapeutic field already faces significant scrutiny — from insurers, licensing boards, state regulators, and the public. When licensed programs use unsubstantiated regulatory language to market diagnostic capabilities that devices do not legally possess, it:

- Exposes licensed clinicians within those programs to liability from their own licensing boards for failure to provide accurate informed consent.
- Creates consumer harm when families make significant financial and clinical decisions based on implied FDA endorsement that does not exist.
- Undermines public trust in the therapeutic field when the regulatory basis for claims is challenged — potentially harming all programs offering legitimate therapeutic services.
- Sets a precedent that normalizes regulatory misrepresentation as a marketing strategy, raising the bar of misleading claims across the industry.

6.2 The Neurofeedback Industry

The neurofeedback field has worked for decades to establish evidence-based credibility. When companies use "FDA registered" as a synonym for "FDA approved" or "FDA endorsed," it:

- Misleads practitioners who may not know the difference and repeat inaccurate language to clients, insurers, and referral sources.
- Creates a race to the bottom — if registration is marketed as equivalent to clearance or approval, there is no incentive for manufacturers to pursue the more rigorous 510(k) process.
- Harms companies that have done the work of obtaining legitimate 510(k) clearances by allowing uncleared or inadequately marketed competitors to claim equivalent regulatory standing.
- Invites FDA scrutiny of the entire field, not just the companies making problematic claims — as seen in the NeuroField warning letter, which sent ripples through the industry.

6.3 What Accurate Language Looks Like

Practitioners, program operators, and marketing professionals should use the following as a guide:

SITUATION	INACCURATE LANGUAGE	ACCURATE LANGUAGE
Device with 510(k) clearance	"FDA approved" / "FDA registered"	"FDA cleared under 510(k) [number] for relaxation training"
Establishment registration only	"FDA registered technology" as quality/safety claim	"The manufacturer is registered with the FDA as required by law" — with no implied endorsement
Clinical claims beyond cleared use	"Our qEEG differentiates ADHD from anxiety"	"qEEG provides brainwave data; clinical interpretation is performed by a licensed clinician within their scope of practice"
Informed consent	No disclosure of regulatory status	Clear disclosure of device clearance status and the distinction between cleared use and any off-label clinical application
Marketing materials	"FDA approved / certified / endorsed"	"FDA cleared" (if 510(k) exists) — never "approved" for a cleared device

Section 7: Complete Reference List

A — FEDERAL LAW & CODE OF FEDERAL REGULATIONS

[A1] [21 CFR § 882.5050 — Biofeedback Device](#)*Electronic Code of Federal Regulations (eCFR) — U.S. Government Publishing Office*The primary federal regulation governing all biofeedback devices including EEG neurofeedback. Defines the device, establishes Class II classification, and specifies the 510(k) exemption criteria.

[A2] [21 CFR § 882.1400 — Electroencephalograph](#)*Electronic Code of Federal Regulations (eCFR)*Governs clinical EEG recording devices. Class II, requires 510(k) clearance. Relevant when a neurofeedback device claims clinical EEG recording functions.

[A3] [21 CFR § 882.1440 — Neuropsychiatric Interpretive EEG Assessment Aid](#)*Electronic Code of Federal Regulations (eCFR)*Governs devices providing interpretive assessments of neuropsychiatric conditions using EEG. Class II with special controls. Includes requirement that device design must prevent stand-alone diagnostic use.

[A4] [21 CFR Part 882 — Neurological Devices \(Full Text\)](#)*Electronic Code of Federal Regulations (eCFR)*Complete Part 882 regulation covering all neurological medical devices including all EEG-related device categories.

B — FDA GUIDANCE & CONSUMER INFORMATION

[B1] [Are There 'FDA Registered' or 'FDA Certified' Medical Devices? How Do I Know What Is FDA Approved?](#)*FDA.gov — Center for Devices and Radiological Health (CDRH). Last updated March 2021.*FDA's definitive consumer guidance explicitly stating that establishment registration does not denote product approval, clearance, or authorization — and that fraudulent 'FDA Registration Certificates' constitute misbranding.

[B2] [Premarket Notification 510\(k\) — Overview](#)*FDA.gov — Center for Devices and Radiological Health* Official FDA explanation of the 510(k) pathway, substantial equivalence standard, and when submission is required.

[B3] [Premarket Approval \(PMA\) — Overview & PMA Approvals Database](#)*FDA.gov — Center for Devices and Radiological Health* Official FDA description of the PMA pathway for Class III high-risk devices. Explains why 'FDA approved' and 'FDA cleared' are not interchangeable.

[B4] [Medical Device Safety and the 510\(k\) Clearance Process](#)*FDA.gov — Center for Devices and Radiological Health* FDA's explanation of how 510(k) and PMA pathways apply to different risk levels, and how the agency balances patient access with safety oversight.

[B5] [Classify Your Medical Device](#)*FDA.gov — Device Advice: Comprehensive Regulatory Assistance* FDA's guide to the three device classes and how intended use and risk level determine classification requirements.

C — FDA DEVICE DATABASE RECORDS (510(K) CLEARANCES)

[C1] [510\(k\) K990538 — BrainMaster 2E / BrainMaster Technologies Inc. \(Cleared May 1999\)](#)*FDA Devices@FDA / CDRH 510(k) Database — accessdata.fda.gov* One of the earliest 510(k) clearances for an EEG neurofeedback system in the U.S. Cleared under 21 CFR 882.5050. Cleared indicated use: relaxation training using alpha EEG biofeedback.

[C2] [510\(k\) K122879 — EEGer4 / EEG Software LLC \(Cleared January 2013\)](#)*FDA CDRH 510(k) Database — accessdata.fda.gov/cdrh_docs/pdf12/K122879.pdf* 510(k) clearance letter and summary for EEGer4 neurofeedback software. Classified as Biofeedback Device, HCC. Has served as the primary predicate device for multiple subsequent neurofeedback 510(k) submissions.

[C3] [510\(k\) K222101 — Prism / GrayMatters Health Ltd. \(Cleared March 2023\)](#)*FDA CDRH 510(k) Database — accessdata.fda.gov/cdrh_docs/pdf22/K222101.pdf* Clearance for a Software as Medical Device for PTSD patients as adjunct to standard care. Cleared under 882.5050, Class II. Primary predicate: EEGer4 (K122879).

[C4] [FDA Product Classification Database — Biofeedback Device \(HCC\)](#)*FDA CDRH Product Classification Database — accessdata.fda.gov* Official product classification record for all Biofeedback Devices (Product Code HCC). Shows regulation number, device class, and applicable review panel.

[C5] [FDA 510\(k\) Premarket Notification Searchable Database](#)*FDA CDRH — accessdata.fda.gov* Searchable database of all cleared 510(k) devices. Use to verify clearance status by device name or manufacturer.

D — FDA ENFORCEMENT ACTIONS

[D1] [Warning Letter — NeuroField, Inc. 621767 \(February 28, 2022\)](#)*FDA.gov — Office of Inspections and Investigations / Warning Letters Database* Full text of the FDA Warning Letter to NeuroField, Inc. Cites the company's registration as a biofeedback device under 882.5050 while making claims exceeding that classification. Foundational for understanding the intended-use boundary and consequences of exceeding it.

E — PROFESSIONAL SOCIETY STANDARDS

[E1] [Standards for Performing Biofeedback](#)*Association for Applied Psychophysiology and Biofeedback (AAPB) — aapb.org* AAPB's official standards document co-developed with BCIA and ISNR (2008). States that advertising claims must either match the FDA label of the equipment or be supported by peer-reviewed literature. Directly relevant to how practitioners should represent their devices.

[E2] [Guidelines for Practice — Neurofeedback](#)*International Society for Neurofeedback and Research (ISNR) — isnr.org* ISNR's official practice guidelines. Recommends use of hardware and software that meets IEEE standards or has been FDA registered (at minimum) for clinical use. Addresses practitioner qualifications, scope of practice, and informed consent.

[E3] Standards of Practice for Neurofeedback and Neurotherapy: A Position Paper of the ISNR Hammond, D.C. et al. (2011). *Journal of Neurotherapy*, 15(1), 54–82. Taylor & Francis Online. The foundational ISNR position paper on standards of practice. Covers ethical advertising and states that 'serious harm is done to the scientific credibility of neurofeedback by advertising based on unsubstantiated claims.'

F — COMPANY WEBSITES CITED (PUBLICLY ACCESSIBLE AS OF APRIL 2026)

[F1] BrainMaster Technologies — About Us Page brainmaster.com/about-brainmaster/ Source of 'FDA registered' language used to describe 510(k) clearances; promotion of uses beyond cleared intended use.

[F2] BrainMaster Technologies — FDA Registration Knowledge Base brainmaster.com/kb-entry/brainmaster-us-fda-registration-information/ BrainMaster's own detailed regulatory status page. Contains both accurate (510(k) numbers, cleared intended use) and inaccurate (extending clearance scope) information.

[F3] Neurologics — Homepage neurologics.com Source of 'FDA-registered technology' hero banner and feature list language; programs for TBI, dementia, ADHD, autism, addiction with no disclosure of cleared intended use.

[F4] Neurologics — FAQ Page neurologics.com/about/faq/ Source of safety question answered with 'FDA-registered technology' as primary evidence of safety.

[F5] Skyterra Young Adult — Homepage skyterrayera.com Source of 'FDA-registered Neurologics brain mapping' as hero headline; diagnostic claims for ADHD differentiation, TBI detection, and addiction circuitry mapping in a licensed residential program serving ages 18–29.

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