Datasea's BCI Product NeuroVibe Completes U.S. FDA Medical Device Registration for Commercial Availability and Market Development in the United States

The NeuroVibe Biofeedback System, including NV-02 and NV-03, has completed U.S. FDA Establishment Registration and Device Listing and is classified as a Class II medical device within the Neurology regulatory area

July 2026 Milestone | The NeuroVibe Biofeedback System, including NV-02 and NV-03, has completed its U.S. FDA Establishment Registration and Device Listing. The products are listed under product code HCC and regulation number 21 CFR 882.5050, and are classified as Class II medical devices within the Neurology regulatory area. This represents a key milestone as Datasea advances from technology prototype development toward defined products, compliant commercialization and international brand development.

What Matters Is an Intelligent Streamlined Approach

As brain-computer interface (BCI) technology continues to evolve across healthcare technology, neurotechnology and digital health applications, the focus is shifting from early-stage concepts to products that can be clearly defined, responsibly engineered and supported by an appropriate regulatory pathway.

For Datasea, the completion of FDA Establishment Registration and Device Listing for NeuroVibe represents more than an administrative milestone. It reflects the Company's continued transition from acoustic technology development toward a more defined medtech product platform. In this transition, three elements are particularly important: differentiated underlying technology, an engineered product architecture, and a compliance pathway that supports responsible market development.

NeuroVibe brings these elements together through Datasea's acoustic AI approach, integrating acoustic stimulation, tVAS neuromodulation, EEG signal acquisition and AI-assisted biofeedback capabilities. The Company believes this platform can support its broader strategy to expand from acoustic high-tech applications into next-generation brain health technology and non-invasive neurotechnology.

This milestone marks a transition of Datasea's acoustic medical technology from research and development results into a more clearly defined, regulated and commercially verifiable product stage.

NeuroVibe provides real-time biofeedback by collecting and analyzing human physiological signals, supporting biofeedback training, brain health management and related wellness-oriented applications. HCC corresponds to the FDA classification of a Biofeedback Device, which provides regulatory boundaries for the product's intended use, labeling and quality management, while also establishing a compliance foundation for subsequent channel validation in the U.S. market.

Transitioning to Acoustic BCI: Datasea Is Building a Non-Invasive Closed Loop

NeuroVibe follows Datasea's acoustic brain-computer interface technology path by integrating four capabilities: acoustic stimulation, tVAS neuromodulation, EEG signal acquisition and AI-assisted health management. Together, these capabilities are designed to form a stimulation-collection-analysis-feedback

loop: the device delivers controlled acoustic input, collects physiological signals, uses AI algorithms to identify changes in user status, and provides real-time biofeedback to support brain health management and wellness-oriented training.

The completion of FDA listing is a key milestone in the international strategy of Datasea. As an innovative company focused on the Acoustic BCI technology path, Datasea integrates acoustic stimulation, tVAS neuromodulation, EEG signal acquisition and AI-assisted health management capabilities. The successful registration and listing of the NeuroVibe Biofeedback System provides an important compliance foundation for the Company's U.S. market development strategy. The Company expects to focus on compliant applications aligned with the product's listed classification, intended use, labeling and applicable FDA requirements, including brain health management, biofeedback training, wellness-oriented applications and professional health service settings.

Productization Logic | Datasea's value does not lie in replicating a traditional EEG device. It lies in integrating acoustic intervention, neural signals, AI algorithms and feedback mechanisms into a continuously iterative system. Once the closed loop is stabilized, product competition may shift from hardware specifications to data, algorithms, individual models and scenario adaptability.

Technical Results: From Reading Signals to Enhancement, Understanding and Feedback

Datasea has disclosed two core acoustic-driven BCI systems. The first is an acoustic-coupled EEG ignal enhancement system, which aims to improve the signal-to-noise ratio and data integrity of non-invasive EEG acquisition through acoustic field coupling. The second is a real-time closed-loop vibration-enhanced BCI system, which aims to connect real-time acoustic stimulation, signal decoding and feedback regulation.

On this basis, the Company is further advancing the technology toward applied systems. One route focuses on communication and care assistance, exploring how neural signals may be converted into external device control commands. Another route focuses on upper-limb rehabilitation robots, exploring how decoded user intent may be converted into structured control logic for training devices. Certain system components have entered the engineering stage, with testing priorities shifting from algorithmic feasibility to stability, response speed and adaptability across different use scenarios.

These results show that Datasea is no longer limited to the single question of whether sound waves can influence brain signals. Instead, the Company is building a complete a technical chain: acoustic coupling enhances raw signals, algorithms extract individualized features, closed-loop systems generate feedback, and execution interfaces connect with health robots or rehabilitation devices. This complete technical chain is important because it may determine whether Datasea's acoustic BCI technology can ultimately support defined products, scalable platforms and sustainable service models.

FDA establishment registration and device listing do not, by themselves, constitute FDA approval, clearance, certification or endorsement of a medical device. NeuroVibe's marketing, labeling, distribution and use remain subject to applicable FDA requirements, including product classification, intended use, quality system requirements and post-market obligations.