Datasea Announces FDA Registration and Device Listing for NeuroVibe Acoustic BCI Biofeedback System as a Class II 510(k)-Exempt Biofeedback Medical Device

BEIJING, August 11, 2026 /PRNewswire/ -- Datasea Intelligent Technology Ltd. (NASDAQ: DTSS) ("Datasea" or the "Company"), a technology company focused on acoustic high-tech and AI multimodal digital solutions, today announced that Shuhai Jingwei (Shenzhen) Information Technology Co., Ltd. ("Shuhai Jingwei"), the Company's variable interest entity in China, has completed establishment registration and device listing with the U.S. Food and Drug Administration ("FDA") for its NeuroVibe Biofeedback System, including products NV-02 and NV-03. The products are listed under FDA product code HCC as Class II 510(k)-exempt biofeedback medical devices within the Neurology regulatory area. FDA establishment registration and device listing do not constitute FDA approval, clearance or authorization of the establishment or the listed devices.

Innovative Vibro-Acoustic Neuromodulation Technology Provides a New Non-Pharmacological Pathway for Clinical Applications

The Company believes that Shuhai Jingwei's initiation of FDA establishment registration and device listing for NeuroVibe, and the products' listing as Class II 510(k)-exempt biofeedback medical devices, is one step forward from the research and development stage to a more clearly defined, regulated product platform with a potential for commercial deployment. It is a key step in translating technological value into clinical and market applications.

The initiation of NeuroVibe's device listing is an important step in Datasea's international commercialization strategy," said Zhixin Liu, Chief Executive Officer of Datasea. "NeuroVibe integrates acoustic intelligence, AI-assisted analysis and non-invasive brain-computer interface technology. We believe this milestone strengthens Datasea's positioning in next-generation brain health technology and it lays the foundation for product iteration, market validation and U.S. and global adoption."

Technology Architecture: A Non-Invasive Platform Combining Acoustic AI and Closed-Loop Biofeedback

NeuroVibe is designed as a non-invasive biofeedback platform integrating four core technology modules: (1) acoustic stimulation, which uses acoustic input at specific frequencies to modulate neural states; (2) tricuspid valve annulus size (tVAS) neuromodulation, or transcranial vibro-acoustic stimulation, which enables non-invasive neuromodulation; (3) electroencephalogram (EEG) signal acquisition, which collects and analyzes brainwave physiological signals in real time; and (4) AI-assisted health management, which provides intelligent analysis and feedback optimization based on individual patient data.

Through this architecture, the system is able to collect and analyze human physiological signals and provide real-time biofeedback to support neurological function assessment and training, brain health management and related wellness-oriented applications.

Differentiated Pathway: From Hardware Device to a Data- and Software-Enabled Brain Health Technology Platform

Datasea's differentiated strength lies in its acoustic AI technology pathway. NeuroVibe is not designed merely as an EEG data acquisition device. Rather, it is intended to integrate acoustic physical input, neural signal acquisition, AI-driven analysis and feedback mechanisms into a closed-loop system. The Company believes this structure may support the evolution of the product from a single hardware device toward a data- and software-enabled brain health technology platform.

The Company has previously announced two acoustic-driven brain-computer interface (BCI) systems that support its strategic plan to develop innovative medical technology. The first is an acoustic-coupled EEG signal enhancement system, which is designed to enhance EEG signal quality through acoustic physical fields. The second is a closed-loop vibration-enhanced BCI system, which is designed to enable a real-time closed loop between vibration stimulation and neural feedback. These systems are intended to support signal enhancement, individualized feature extraction, feedback regulation and potential integration with intelligent health devices and rehabilitation-support scenarios.

Commercialization Pathway: Focusing on Regulatory-Compliant Application Scenarios and Expanding Non-Pharmacological Intervention Pathways

Datasea expects that NeuroVibe's early commercialization efforts in the U.S. market will focus on regulatory-compliant application scenarios aligned with the product classification and intended use listed. Potential application areas include brain health management, supporting neurological function assessment and dynamic tracking; biofeedback training, enabling real-time visualization of physiological signals and self-regulation; stress relaxation, through vibro-acoustic coupling to modulate the autonomic nervous system; sleep improvement, through closed-loop intervention based on brainwave rhythms; and, cognitive maintenance, including support for attention, memory and other cognitive functions.

The Company believes that with the growing demand for non-pharmacological and non-invasive health technologies, NeuroVibe's technology pathway represents immense potential for the expansion of its medtech product applications.

Company Outlook

Datasea believes that Shuhai Jingwei's initiation of NeuroVibe's listing as Class II 510(k)-exempt biofeedback medical devices further strengthens the Company's strategic positioning in acoustic intelligence, AI-driven health technology and non-invasive neurotechnology. The Company plans to continue advancing product iteration, regulatory compliance, channel development and application validation with the goal of building a scalable acoustic AI technology platform for brain health, intelligent interaction and the global health technology market.

About Datasea Intelligent Technology Ltd. (NASDAQ: DTSS)

Datasea Intelligent Technology Ltd. is a Nasdaq-listed technology holding company focused on acoustic high-tech innovation and AI-powered multimodal digital solutions. The Company focuses on the development and commercialization of products, services, and solutions across acoustic high-tech and AI agent multimodal digitalization.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements involving risks and uncertainties, including but not limited to statements regarding the commercialization progress of the Company's products in target markets, compliance with regulatory obligations, market validation results, product iteration plans, channel development, application expansion and future business prospects. Actual results may differ materially from those expressed or implied by these forward-looking statements. Investors should not place undue reliance on these statements. Further information regarding risks and uncertainties is included in the Company's filings with the U.S. Securities and Exchange Commission. The Company undertakes no obligation to update any forward-looking statement except as required by applicable law.

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