Press Release
FOR IMMEDIATE RELEASE

CorTec Receives FDA Breakthrough Device Designation for Its Brain Interchange System in Stroke Rehabilitation — the First BCI Worldwide Designated for Stroke Motor Rehabilitation

Freiburg, Germany, April 08, 2026 — CorTec GmbH, a pioneer in fully implantable brain-computer interfaces (BCI), today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation for the company's Brain Interchange™ system. The designation covers the use of direct cortical electrical stimulation to support motor recovery in people living with chronic stroke-related impairments.

The Breakthrough Device Designation is granted to medical technologies that have the potential to provide more effective treatment for life-threatening or irreversibly debilitating conditions. The program is designed to facilitate medical device development and review through prioritized and more interactive engagement with the FDA.

CorTec's Brain Interchange system combines neural signal recording with adaptive stimulation in a closed-loop system. The platform is currently being evaluated in an FDA-approved IDE study at the University of Washington in Seattle, marking the first clinical investigation of a fully implantable, wireless BCI system for stroke rehabilitation in humans.

Stroke is the leading cause of acquired long-term disability in adults worldwide. Approximately 9 million ischemic strokes occur globally each year, with an estimated 1.7 million cases in the United States and Europe alone. Over 80% of stroke patients experience upper-limb impairment, and approximately 50% remain permanently disabled despite standard rehabilitation. For chronic stroke patients with moderate-to-severe motor deficits whose recovery has plateaued after conventional therapy, no approved implantable treatment exists today.

"Only a few BCI companies worldwide – including Neuralink, Synchron, or Blackrock Neurotech - have received Breakthrough Device Designation to date. Achieving this designation is a defining milestone for CorTec and underscores the potential of our Brain Interchange system to address the significant unmet need in stroke rehabilitation," said **Dr. Frank Desiere, CEO of CorTec**. "Together with promising initial results from our first-in-human study in Seattle as well as additional long-term data published in Nature Scientific Data[1] demonstrating signal stability over 500 days, this designation provides strong momentum as we advance toward larger clinical trials. We believe CorTec occupies a unique position in the global BCI landscape, combining a fully implantable, bidirectional closed-loop platform with a therapeutic approach focused on restoring motor function after stroke."

CorTec's approach represents a distinct direction within the global BCI field. While a number of BCI systems have received Breakthrough Device Designation and are restricted to enable patient communication by controlling digital devices through thought, the Brain Interchange™ platform is being developed as a fully implantable, bidirectional device, enabling brain-based communication but also therapeutic neurostimulation, e.g. allowing to restore motor function after stroke. At present, no other BCI company worldwide holds a Breakthrough Device Designation for this indication.

"The Breakthrough Device Designation enables more frequent and structured engagement with the FDA as we advance our development program," said **Mara Assis, Head of Regulatory Affairs & Quality Management at CorTec**. "Our regulatory strategy has followed a stepwise approach, from prior device clearance to IDE approval and successful human implantations. This designation will help accelerate planning of clinical trials and support the next regulatory milestones."

CorTec continues to advance the Brain Interchange System as a flexible, adaptive platform with potential applications across multiple neurological conditions. In addition to the ongoing stroke rehabilitation study, the Brain Interchange platform is being evaluated for epilepsy, with further indications including paralysis and depression under development.

[1] https://www.nature.com/articles/s41597-025-06359-w

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Forward-Looking Statements: This press release contains forward-looking statements regarding CorTec's regulatory strategy and clinical development plans. Actual results may differ materially. The FDA Breakthrough Device Designation does not change the requirements for marketing authorisation and does not guarantee approval.

About Brain Interchange™

Brain Interchange™ is a proprietary brain-computer interface platform developed and owned by CorTec GmbH. The fully implantable, wireless investigational system is designed for long-term neural recording and adaptive stimulation, allowing bi-directional brain-based communication for the severely paralyzed, and also enabling the discovery and development of next-generation closed-loop neuromodulation therapies across a range of neurological and psychiatric conditions.

Learn more at www.brain-interchange.com or follow the Brain Interchange on LinkedIn.

Clinical Evidence Underpinning the Designation

The Breakthrough Device Designation is supported by a robust regulatory and clinical development pathway. Following FDA 510(k) clearance for cortical mapping electrodes in 2019, CorTec demonstrated the first successful beta-phase–locked closed-loop stimulation in a 2023 feasibility study at the University of Washington, Seattle, USA.

After Investigational Device Exemption (IDE) approval in 2024, the first two patients were implanted at Harborview Medical Center in Seattle in July 2025 and February 2026, with the first patient showing meaningful neurological improvement, including recovery of upper-limb motor function that had previously plateaued with conventional therapy.

The Brain Interchange system has demonstrated more than 500 days of continuous stability, as reported in a peer-reviewed publication in *Nature Scientific Data*[1], and is also being evaluated in an FDA-registered epilepsy study at Mayo Clinic, supporting its multi-indication platform design.

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About CorTec

CorTec GmbH is a German neurotechnology company founded in 2010 in Freiburg. The company operates a dual business model comprising its proprietary Brain Interchange BCI platform and a growing contract development and manufacturing (CDMO) division. CorTec is the first European company to bring a fully implantable, bidirectional BCI system into FDA-approved clinical evaluation in the United States. CorTec's growth is supported by strategic investors including High-Tech Gründerfonds, KfW, K&SW Invest, LBBW Venture Capital, Mangold Invest, M-Invest and Santo Venture Capital GmbH.

Learn more at www.cortec-neuro.com or follow CorTec on LinkedIn.

Contact:
CorTec GmbH
Carolina Remke – Head of Marketing
pr@cortec-neuro.com
www.cortec-neuro.com
Phone.: +49 (0)761 70 888 200
Neuer Messplatz 3
79108 Freiburg – Germany

Media Support:
MC Services AG
Katja Arnold, Dr. Johanna Kobler, Kaja Skorka
cortec@mc-services.eu
Phone.: +49 (0)89- 210 228-0