Press Release
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CorTec Receives Second FDA Breakthrough Device Designation for Brain Interchange™

One Platform, Two FDA-Recognized Indications: Stroke Rehabilitation and Communication

Freiburg, Germany, August 31, 2026 — A cursor on a screen is a small thing, unless it is the only part of the world you can still move. CorTec GmbH, a pioneer in fully implantable brain-computer interfaces (BCI), today announced that the U.S. Food and Drug Administration (FDA) has granted a second Breakthrough Device Designation for its Brain Interchange™ system to include communication. The designation covers non-progressive quadriplegia, giving people with paralysis in all four limbs a way to control a computer cursor through thought alone and establish a direct and independent channel of communication with the digital world. Spanning both therapy and communication on a single implant, CorTec's two FDA Breakthrough Device Designations place it among a small, global elite in BCI and, by its own account, make it the only company in the space designated for stroke motor rehabilitation.

The FDA grants Breakthrough Device Designation to technologies with the potential to more effectively treat or diagnose life-threatening or irreversibly debilitating conditions, speeding their development through a prioritized, interactive review pathway.

Brain Interchange spans two domains of brain-computer interfacing in a single implant. As a therapeutic BCI, it stimulates the brain to drive recovery, the basis of its stroke motor rehabilitation program. As an assistive BCI, it decodes intention to restore control — the domain of the new communication designation. Together, the two designations support the premise behind the platform: one implantable system, many neurological conditions.

The results are already speaking for themselves. In CorTec's ongoing study in stroke at the University of Washington, a study participant demonstrated computer control through thought using the same implant, illustrating the capability the communication program will now investigate under structured FDA engagement.

Non-progressive quadriplegia — for example following spinal cord injury — leaves people with fully intact cognitive function but a lasting loss or impairment of voluntary movement in all four limbs, its severity depending on the level and completeness of the injury. For many, operating a computer independently is out of reach. By enabling direct cursor control through thought, Brain Interchange aims to give these patients a stable, self-directed channel to the electronic devices that run daily life.

Brain Interchange records cortical signals and translates them into digital commands in real time. Built as a bidirectional, closed-loop system, it both reads neural activity and delivers targeted electrical stimulation. The same architecture serves both designated indications on identical hardware: decoding movement intention for communication and delivering therapeutic cortical stimulation for motor recovery after stroke.

"This second designation confirms the platform strategy behind Brain Interchange" said Dr. Frank Desiere, CEO of CorTec. "To our knowledge, only a handful of BCI companies worldwide, among them Neuralink and Paradromics, hold more than one FDA Breakthrough Device Designation, and no other system is designated for stroke motor rehabilitation. We built one implantable system to fight

multiple neurological conditions, and the FDA has now recognized its breakthrough potential in two of them. Our job now is to turn that recognition into approved therapies that reach patients."

"Designing Brain Interchange as an indication-agnostic platform from day one is exactly why it was possible to move so quickly through this process," said **Mara Assis, Head of Regulatory Affairs & Quality Management at CorTec**. "The platform rests on more than a decade of building brain interfaces — over 50 of our electrodes have been implanted in humans — and that progress is what carries a designation from paper into a clinical program."

Stroke motor rehabilitation remains CorTec's lead clinical program. Brain Interchange is under evaluation in an FDA-approved IDE study at the University of Washington in Seattle, where three patients have been implanted to date, and it has demonstrated more than 500 days of continuous signal stability in *Nature's* peer-reviewed journal *Scientific Data*. The platform is also being evaluated in a registered epilepsy study at Mayo Clinic (NCT05439655), with 13 patients enrolled to date, and an upcoming communication study in paralysis at UMC Utrecht (INTENSE); further indications, including depression, are in development. CorTec is enrolled in the FDA's Total Product Life Cycle Advisory Program (TAP) for its stroke program.

Brain Interchange at a glance

- Two FDA Breakthrough Device Designations: stroke motor rehabilitation (April 2026) and communication (August 2026).
- To CorTec's knowledge, the only BCI worldwide designated for stroke motor rehabilitation.
- Fully implantable, wireless, battery-free, bidirectional and closed-loop.
- More than 500 days of continuous signal stability, published in *Nature Scientific Data*.
- Non-penetrating cortical surface electrodes; no electrodes enter brain tissue.
- Three systems implanted in the FDA-approved IDE study in Seattle.
- 13 patients enrolled in the registered epilepsy study at Mayo Clinic.
- More than 50 CorTec cortical electrodes implanted in humans over more than a decade.
- Enrolled in the FDA Total Product Life Cycle Advisory Program (TAP).

Media assets

Participant video, UW Medicine (2 min): https://www.youtube.com/watch?v=xNXBe8P4Tz8
Company introduction: https://youtu.be/b-lHrH0IqQA
Nature Scientific Data publication: https://www.nature.com/articles/s41597-025-06359-w

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Disclaimer: The Brain Interchange system is an investigational device and is not approved for commercial use. FDA Breakthrough Device Designation does not change the requirements for marketing authorization and does not guarantee approval. Statements regarding CorTec's plans, future indications, and commercialization intentions are forward-looking and subject to risks and uncertainties.

About CorTec

CorTec GmbH is a clinical-stage neurotechnology company founded in 2010 in Freiburg, Germany, with one purpose: to restore independence to people with neurological conditions. CorTec is developing Brain Interchange™, a fully implantable bidirectional brain-computer interface (BCI) platform currently in FDA-authorized clinical evaluation in the United States — making CorTec the first European company to reach this stage. The device holds two FDA Breakthrough Device Designations: one for stroke motor rehabilitation (April 2026) and a second for communication (August 2026), and it has been admitted to the FDA's Total Product Life Cycle Advisory Program (TAP). CorTec also operates a revenue-generating contract development and manufacturing (CDMO) business, supplying active implantable technology to partners across the global neurotherapy field, extending the reach of these technologies beyond what any single company could achieve alone.

CorTec — fighting neurological conditions with implantable neurotechnology.