Elon Musk's brain implant company is approved for human testing. How alarmed should we be?

Elon Musk's brain-implant company Neuralink last week received regulatory approval to conduct the first clinical trial of its experimental device in humans. But the billionaire executive's bombastic promotion of the technology, his leadership record at other companies and animal welfare concerns relating to Neuralink experiments have raised alarm.

"I was surprised," said Laura Cabrera, a neuroethicist at Penn State's Rock Ethics Institute about the decision by the US Food and Drug Administration to let the company go ahead with clinical trials.
Musk's erratic leadership at Twitter and his "move fast" techie ethos raise questions about Neuralink's ability to responsibly oversee the development of an invasive medical device capable of reading brain signals, Cabrera argued. "Is he going to see a brain implant device as something that requires not just extra regulation, but also ethical consideration?" she said. "Or will he just treat this like another gadget?"
Neuralink is far from the first or only company working on brain interface devices. For decades, research teams around the world have been exploring the use of implants and devices to treat conditions such as paralysis and depression. Already, thousands use neuroprosthetics like cochlear implants for hearing. But the broad scope of capabilities Musk is promising from the Neuralink device have garnered skepticism from experts.

Neuralink entered the industry in 2016 and has designed a brain-computer interface (BCI) called the Link – an electrode-laden computer chip that can be sewn into the surface of the brain and connects it to external electronics – as well as a robotic device that implants the chip.
The design appears to use a novel kind of electrode, said John Donoghue, a neuroscientist at Brown University who led the team that developed the brain-computer interface 'BrainGate' to restore movement for people with paralysis.
Musk has claimed Neuralink's device could be used for a range of therapeutic uses, to treat conditions like blindness, paralysis, depression. But he has also said that the eventual aim is to create a "general population device" that could connect a user's mind directly to supercomputers and help humans keep up with artificial intelligence. He has also suggested that the device could eventually extract and store thoughts, as "a backup drive for your non-physical being, your digital soul." The company is not there yet. So far, Neuralink has tested its chips on animals. A video released in 2021 shows a monkey using the device to play the video game Pong with his mind and another from 2022 appeared to show a monkey typing on a computer telepathically.

The FDA approval cleared the first hurdle toward a human clinical trial, but the scope, focus and design of any such study remains unclear.
In a statement, a spokesperson for the FDA would only confirm that Neuralink was approved for an investigational device exemption (IDE) – the FDA process that allows a device to be used for clinical studies. The FDA's approval last week comes after the regulator initially rejected Neuralink's previous bid for clinical trials in 2022, citing "dozens of deficiencies" the company had to address before human testing, according to a report from Reuters.

According to the news agency, safety concerns related to the implant's lithium battery and potential overheating, questions over whether the machine's small wires could migrate to other parts of the brain and that the device cannot be removed without damaging brain tissue.
It is unclear how these concerns were resolved. The FDA declined to comment specifically on Neuralink's application process, but the spokesperson commented generally that the agency has a "scientifically rigorous process to evaluate the safety and effectiveness of medical devices". She added that the FDA has "a deep commitment to ensure the responsible and humane care of animals" involved in testing.
Neuralink declined to comment on its plans for clinical trials.

Kari Paul and Maanvi Sing, *The Guardian,* 4 Jun 2023