



Written by [Luis Miguel](#) on March 6, 2023

## Report: FDA Rejected Musk's Bid for Human Trials of Brain Implant

Elon Musk's quest to turn humanity into a race of cyborgs has been slapped with a temporary hurdle. While he and his supporters would consider it a hindrance to scientific progress, is this one area where we would be better off treating lightly — or even staying off the road entirely?

According to a report by [Reuters](#), the FDA blocked the request of Musk's medical device company, Neuralink, to begin human trials on its brain implant.

The request was made in early 2022, and the rejection was not made publicly known until now.



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The U.S. Food and Drug Administration made its decision based on several concerns, including the danger of the device's tiny wires (which are thinner than a human hair) migrating to parts of the brain they aren't supposed to and the safety of the product's lithium battery.

In addition, regulators want to know whether the implant, once inserted, can be removed, and if this can be done without damaging the brain.

In total, the FDA listed dozens of issues that Neuralink must resolve to qualify for human testing. Although Musk [stated](#) in a presentation back in November that he expects human trials to begin this spring, three Neuralink employees who spoke with Reuters said they doubt the company will resolve the long list of issues anytime soon.

Musk has not held back in articulating a very bold vision for Neuralink. He has said his brain implants will allow the disabled to walk again and cure everything from autism to depression to blindness to obesity. It will even, Musk adds, allow for people to surf the internet with their minds.

Musk has also said that using these brain implants to turn human beings into cyborgs is the key to allowing mankind to survive in the age of AI

"I don't love the idea of being a house cat, but what's the solution?" he [said](#) at a Vox Media Code of Conference in 2017. "I think one of the solutions that seems maybe the best is to add an AI layer [to humans]."

Musk's claims about his brain implant almost have a messianic ring to them. It'll make the blind see, the lame walk, and bring salvation to the human race.

And while some observers may still believe that real-life cyborgs are the stuff of science fiction, it would be unwise to doubt the capabilities of the man who has successfully launched two innovative tech startups, electric car company Tesla, and rocket builder SpaceX.

"I definitely would never bet against him," said Bob Nelsen, co-founder of venture capital firm ARCH



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Venture Partners, in a statement to Reuters.

Nelsen, who says he has invested in Neuralink, added, “If he has some bumps in the road with Neuralink, or any other thing, he’ll regroup and figure it out.... Just think about it: Those are hard industries with huge safety barriers — cars and rockets.”

Moreover, Musk has claimed that he is so certain of Neuralink’s safety he would implant it in his own children.

And the progress made by one of Neuralink’s biggest competitors shows that the technology is closer than ever before to becoming a reality, whether Musk is the first person to bring it to market or not.

Synchron, which is working on its own brain computer interface (BCI), already has approval from the FDA to perform human trials. For this reason, Musk [attempted to make a deal](#) with them in August.

BCIs work by emitting electrodes that penetrate the brain or sit on the surface to allow the brain to connect to computers.

But if Neuralink is currently experiencing woes due to the lack of human tests, that may change soon thanks to recently passed laws that accelerate the FDA review process.

As Reuters reports:

Among a host of policy changes, Congress instituted the “breakthrough” designation for novel devices targeting serious conditions. The label gives companies faster agency feedback during the development process.

The breakthrough-device program, among other changes, has helped the FDA substantially reduce the total time companies spend seeking agency approvals, the FDA says. The agency also must respond to human-trial applications within 30 days.

Of 750 devices currently labeled breakthrough, more than 100 are neurological, the FDA says.

Nevertheless, the stakes are now high for Neuralink after the rejection. The FDA says it approves approximately two-thirds of applications for human trials on the first request. Most companies give up after three attempts because of the high cost in money, time, and research.

It’s also worth noting that Musk’s companies have gotten [billions](#) of dollars in federal subsidies over the years. And he was formerly part of the World Economic Forum crowd, though he has been estranged from them recently. The establishment has certainly been more than happy to further Musk and Neuralink.

This raises the question: As good as Neuralink may sound, can we truly trust that actors such as Big Tech and Big Government won’t use the technology to gain control over our minds?

Consider that no computer is completely impervious to hacking. Do you really want to give the Powers That Be the ability to hack into your brain?



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