Elon Musk's brain-chip venture gets FDA stamp of approval

By Katja Hamilton

26 May 2023

Neuralink - co-founded by Elon Musk - has received US Food and Drug Administration (FDA) approval to launch its first in-human clinical study. This represents the first step to mainstreaming brain-machine interface implants, which are currently focused on giving people with quadriplegia the ability to control their computers and mobile devices with their thoughts.

Source: Pexels

"Congratulations Neuralink team!" Musk asserted in a social media post on Friday, 26 May.

"We are excited to share that we have received the FDA's approval to launch our first-in-human clinical study! This is the result of incredible work by the Neuralink team in close collaboration with the FDA and represents an important first step that will one day allow our technology to help many people," Neuralink tweeted.

Dubbed the N1 Implant, the cosmetically invisible device records neural activity through 1024 electrodes distributed across 64 threads. These highly-flexible, ultra-thin threads detect and record electrical signals produced by the brain's neurons. These signals represent the person's thoughts, intentions, or commands.

Once the neural signals are decoded, the information is wirelessly transmitted from the implanted device to an external

device, such as a mobile device or computer, and the Neuralink Application decodes the data stream into actions and intents.

If, for example, a person intends to move a cursor on a screen, the neural signals are translated into corresponding cursor movements. This involves advanced algorithms that analyse and interpret the patterns and patterns of the neural activity.

Neuralink explained that the threads are so fine that they can't be inserted by the human hand, and consequently, a surgical robot has been designed to reliably and efficiently insert these threads exactly where they need to be in the brain.

> *Our surgical robot uses advanced imaging systems to detect the brain and insert threads away from blood vessels. Here, you can see everything the robot sees while we test the accuracy of each of the robot's high-precision cameras ﷺ #techtuesday pic.twitter.com/c5rklTp2m4— Neuralink (@neuralink) May 23, 2023*

The surgical robot's needle incidentally is thinner than a human hair, and grasps, inserts, and releases the threads.

Hermetically sealed in a biocompatible enclosure that withstands physiological conditions several times harsher than those in the human body, the N1 Implant has been positioned to restore capabilities such as vision, motor function, and speech in the future.

A media source stated that Neuralink - founded in 2016 - sought FDA approval in early 2022 and the agency rejected the application. The FDA cited concerns with the device's lithium battery and the likelihood of the N1 Implant's threads relocating within the brain, issues which needed to be addressed before clinical human trials could be green lighted.

Recruitment is not yet open for Neuralink's clinical trial.

ABOUT KATJA HAMILTON

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