Concerns over Neuralink Chip

Why in news?

Elon Musk's company Neuralink gets the U.S. Food and Drug Administration's (FDA) approval for study of brain implants in humans.

What is Neuralink?

- Neuralink is brain-implant Company, co-founded by Elon Musk.
- Neuralink is making a Class III medical device known as a *brain-computer interface* (BCI).
- The device connects the brain to an external computer via a Bluetooth signal, enabling continuous communication back and forth.

What is the device?

- The device itself is a coin-sized unit called a Link.
- It's implanted within a small disk-shaped cut-out in the skull using a precision surgical robot.
- The robot splices a thousand tiny threads from the Link to certain neurons in the brain.
- Each thread is about a quarter the diameter of a human hair.

What are the benefits of Neuralink?

- If the Neuralink successfully works in humans, it would have wide range of benefits.
- The device could enable precise control of prosthetic limbs, giving amputees natural motor skills.
- It could revolutionise treatment for conditions such as Parkinson's disease, epilepsy, and spinal cord injuries.
- It can also be used in the treatment of obesity, autism, depression, schizophrenia and tinnitus.

What were the FDA's concerns over clinical human trials of Neuralink?

- Neuralink finally received FDA approval for its first human clinical trial in May 2023.
- The FDA had also raised a list of concerns that needed to be resolved before human trials could commence.
- **Safe surgery -** A precision robot known as Implant/r1 performs the surgical procedure to implant the Neuralink BCI.
- This robot should be reliably and safely implant and remove the Neuralink BCI without damaging surrounding brain tissue.
- **Harmful side effects -** The implanted Neuralink BCI must not unintentionally

influence other brain functions.
- It should not cause any unwanted side effects such as seizures, headaches, mood changes, or cognitive impairment.
- **Safe power supply -** Overheating lithium-ion batteries can pose great risk to BCI users.
- **Wire migration -** The Link consists of a disk-shaped chip with very thin wire electrodes that connect to neurons in the brain.
- There is the risk of wire migration over time due to natural movement, inflammation, or scar tissue formation.
- **Implant removal -** The safety and difficulty of removal of implants.
- **Data privacy and security -** Safeguards of the data collected against being hacked, manipulated or otherwise misused.

What Neuralink's reply to the FDA's concerns?

- Extensive animal studies have been conducted by Neuralink.
- It provides evidence that its wires did not migrate significantly over time, or cause any adverse effects on the brain.
- The company also has come up with a method for tracking and adjusting the position of the wires to overcome wire migration.
- Neuralink specially designed battery to evaluate its performance, durability and bio-compatibility.

What is the way ahead?

- Musk has made many radical claims regarding his future vision for the technology beyond its potential medical use.
- He claims Neuralink could augment human intelligence by creating an on-demand connection with artificial intelligence systems.
- For example, improved cognition through enhanced memory, and improved learning and problem-solving skills.
- Neuralink with at this growth pace needs regulation.
- The cutting edge technology must not be released to the public until proven to be safe and this requires exhaustive testing.

Quick Facts

Class III medical device

- The Food and Drug Administration (FDA) has established classifications for different generic types of devices.
- Each of these generic types of devices is assigned to one of three regulatory classes - Class I, Class II and Class III.
    - Class I General Controls
    - Class II General Controls and Special Controls
    - Class III General Controls and Premarket Approval
- It is assigned based on the level of control necessary to assure the safety and effectiveness of the device.

- Class III includes those with the greatest risk like pacemakers and breast implants.
- These devices usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury.
- For Class III devices, a premarket approval application (PMA) is required.

References

1. The Hindu - What were FDA's concerns over Neuralink chip?
2. FDA - Medical Devices

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