U.S. regulators rejected Elon Musk’s bid to test brain chips in humans, citing safety risks

On at least four occasions since 2019, Elon Musk has predicted that his medical device company, Neuralink, would soon start human trials of a revolutionary brain implant to treat intractable conditions such as paralysis and blindness.

Yet the company, founded in 2016, didn’t seek permission from the U.S. Food and Drug Administration (FDA) until early 2022 – and the agency rejected the application, seven current and former employees told Reuters.

The rejection has not been previously reported. In explaining the decision to Neuralink, the agency outlined dozens of issues the company must address before human testing, a critical milestone on the path to final product approval, the staffers said. The agency’s major safety concerns involved the device’s lithium battery; the potential for the implant’s tiny wires to migrate to other areas of the brain; and questions over whether and how the device can be removed without damaging brain tissue, the employees said.

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