

# **FDA warns of consumer devices that claim to diagnose concussion**

April 11 2019

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(HealthDay)—Consumer devices that claim to help assess, diagnose, or

manage concussion and other head injuries are unproven and illegal, and using them could pose serious health risks, the U.S. Food and Drug Administration warns.

"I want to be clear, there are currently no devices to aid in assessing [concussion](#) that should be used by consumers on their own," Jeffrey Shuren, M.D., J.D., director of the FDA Center for Devices and Radiological Health, said in a statement. "Using such devices can result in an incorrect diagnosis after a head injury that could lead a person with a serious injury to return to their normal activities instead of seeking critical medical care, putting them at greater danger."

The FDA is concerned about products that claim to assess and diagnose changes in [brain function](#) by having a person who has suffered a head injury do tests on a smartphone or tablet-based app to detect changes in physical or mental function, including vision, concentration, memory, balance, and speech. Some of those apps are marketed to coaches and parents for use during sporting events.

"Products being marketed for the assessment, diagnosis, or management of a head [injury](#), including concussion, that have not been approved or cleared by the FDA are in violation of the law," Shuren said. "The FDA has alerted companies to our concerns and asked them to remove such claims. We will continue to monitor the marketplace for devices making these unsubstantiated claims and are prepared to take further action if necessary."

**More information:** [More Information](#)

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Citation: FDA warns of consumer devices that claim to diagnose concussion (2019, April 11)

retrieved 9 April 2024 from

<https://medicalxpress.com/news/2019-04-fda-consumer-devices-concussion.html>

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