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FDA allows marketing of first-of-kind computerized cognitive tests

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The Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT) and ImPACT Pediatric are the first medical devices permitted for marketing that are intended to assess cognitive function following a possible concussion.

They are intended as part of the medical evaluation that doctors perform to assess signs and symptoms of a head injury.

The device is manufactured by ImPACT Applications, located in Pittsburgh, Pennsylvania, USA.

ImPACT and ImPACT Pediatric are not intended to diagnose concussions or determine appropriate treatments.

Instead the devices are meant to test cognitive skills such as word memory, reaction time and word recognition, all of which could be affected by a head injury.

The results are compared to an age-matched control database or to a patient's pre-injury baseline scores, if available.

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"These devices provide a useful new tool to aid in the evaluation of patients experiencing possible signs of a concussion, but clinicians should not rely on these tests alone to rule out a concussion or determine whether an injured player should return to a game," said Dr Carlos PeÃ±a, director of the division of neurological and physical medicine devices at the FDA's Center for Devices and Radiological Health.

ImPACT software runs on a desktop or laptop and is intended for those ages 12 to 59, while the ImPACT Pediatric runs on an iPad and is designed for children ages 5 to 11.

Only licensed health care professionals should perform the test analysis and interpret the results.

Traumatic brain injuries account for more than 2 million emergency room visits in the United States each year, according to the US Centers for Disease Control and Prevention, and contribute to the deaths of more than 50,000 Americans.

A significant percentage of these injuries are considered to be mild. A concussion is considered to be a mild traumatic brain injury.

The manufacturer submitted over 250 peer-reviewed articles, of which half were independently conducted clinical research studies.

The research publications analyzed the scientific value of the ImPACT devices including the devices' validity, reliability and ability to detect evidence of cognitive dysfunction that might be associated with a concussive head injury.

The FDA concluded that these studies provide valid scientific evidence to support the safety and effectiveness of the ImPACT and ImPACT Pediatric devices.

The FDA reviewed the ImPACT device through its de novo classification process, a regulatory pathway for novel, low- to moderate-risk medical devices that are first-of-a-kind, for which special controls can be developed, in addition to general controls, to provide a reasonable assurance of safety and effectiveness of the devices.