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FDA authorizes marketing of tool to aid in diagnosis of autism spectrum disorder

by from the Food and Drug Administration

The Food and Drug Administration (FDA) has authorized marketing of a novel medical device to help diagnose autism spectrum disorder (ASD) in patients 18 months through 5 years who are at risk of developmental delay based on parent, caregiver or health care provider concerns. The diagnostic device, Cognoa ASD Diagnosis Aid, should be used in conjunction with patient history and clinical evidence and not as a stand-alone device.

Early diagnosis and treatment for ASD is essential to improve a child's development, but diagnosis can be challenging due to symptom variability. While ASD can be diagnosed as early as 18 months of age, most children are not diagnosed until later in childhood. Diagnostic aids that help pediatricians act on early concerns for developmental delay may allow children with ASD to begin treatment sooner.

The Cognoa ASD Diagnosis Aid is a machine learning-based software, also referred to as software as a medical device, that uses an algorithm to interpret input from parents and caregivers, video analysts and health care providers.

The device includes:

- a mobile app for parents and caregivers who can read at an eighth-grade level or higher to answer questions about the child's behavior and upload videos of the child;
- a portal for trained specialists to analyze videos; and
- a portal for health care providers to answer questions about behavior, track information from parents and caregivers, and review the device report.

If sufficient information has been provided for the algorithm, the device reports a positive or negative diagnosis. If there is insufficient information, the device reports that no result can be generated.

A multicenter study of 425 patients 18 months through 5 years of age compared the device's assessment to an assessment by an expert panel using the standard ASD diagnostic approach. The device did not generate a definitive report in 68% of patients. For the 32% of patients with a definitive report, the device results matched the panel's conclusions for 81% of patients who tested positive for ASD and for 98% of patients who tested negative for ASD by the device. The sensitivity was 98%, and the specificity was 79%.

Although no adverse events were identified in the study, risks associated with device use include misdiagnosis and delayed diagnosis of ASD, which could result in delayed treatment and/or delivery of treatment not appropriate for ASD.

The FDA's Office of Pediatric Therapeutics, Center for Drug Evaluation and Research, Division of Pediatric and

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Maternal Health, and Center for Devices and Radiological Health contributed to this article.

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- FDA approval letter
- Information on software as a medical device