FDA Perspective: Regulatory Considerations for Digital Mental Health Diagnostics

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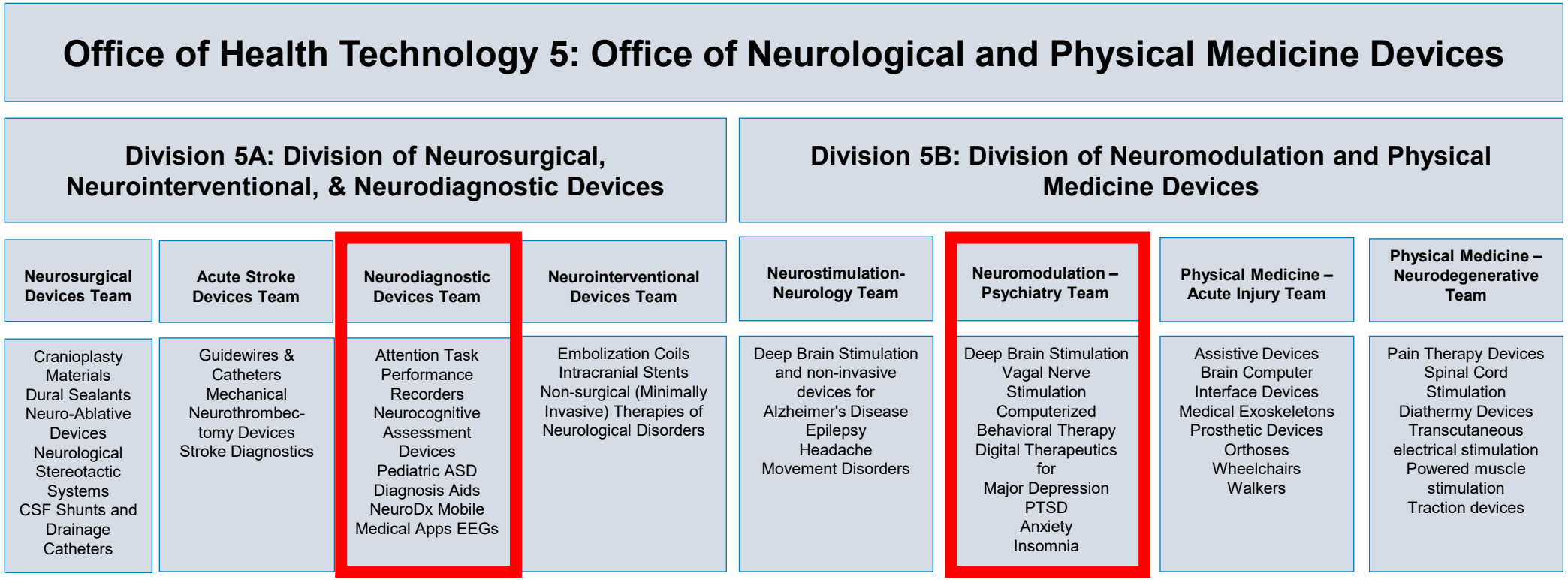
November 6, 2025

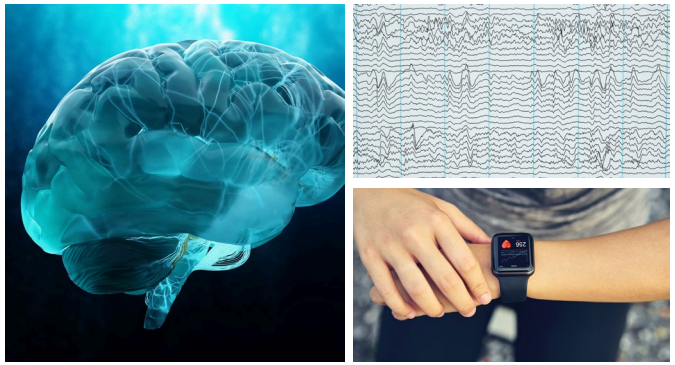
OHT5 – Who We Are



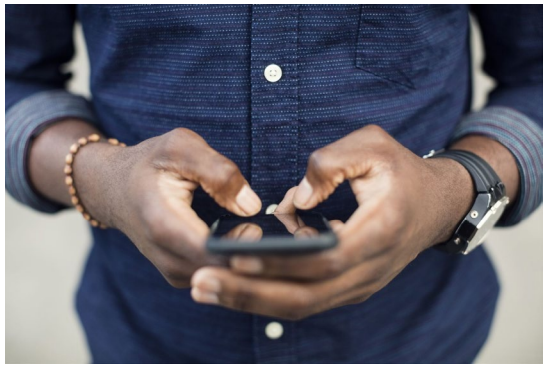
What are Digital Mental Health (DMH) Diagnostic Devices?

- Devices that are intended to contribute to the assessment, evaluation, monitoring, or diagnosis of a patient
- Not limited to “stand-alone” diagnostic tests
- May collect and/or analyze various types of patient data

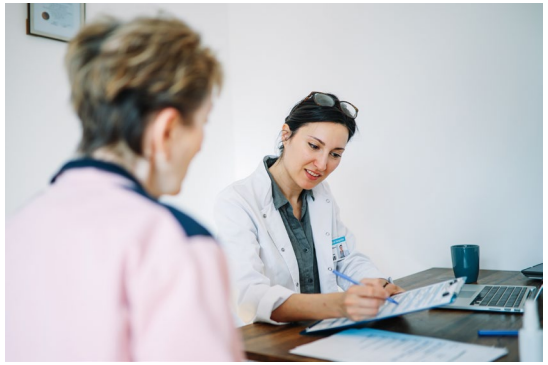
Physiological Measurements



Behavioral Data



Clinical Assessments



Examples of DMH Diagnostic Device Authorizations

Attention Task Performance Recorders (Unclassified)

- Prescription devices intended to aid in the assessment of attention deficit hyperactivity disorder (ADHD) by analyzing patient data to provide measures of hyperactivity, impulsivity, attention/inattention, and inhibitory control. Do not provide a diagnosis or identify presence or absence of a specific medical condition.
  - TOVA (K173915, 2018): Computerized continuous performance test; provides measures of attention and inhibitory control based on analysis of patient responses
  - QbCheck (K143468, 2016): Computerized continuous performance test; provides measures of inattention, hyperactivity, and impulsivity based on patient responses and activity on video

Source: FDA 510(k) Database, 2025 (www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm)

Examples of DMH Diagnostic Device Authorizations

Pediatric Autism Spectrum Disorder (ASD) diagnosis aids (21 CFR 882.1491)

- Prescription devices intended to aid in the diagnosis of ASD in pediatric patients by analyzing patient data to provide clinicians with a statistical estimate of whether an individual may have ASD
  - Canvas Dx (K243558, 2025): Software analysis of scored video and answers to behavioral questions; provides indicators of the presence or absence of ASD
  - EarliPoint System (K243891, 2025): Software and hardware system that analyzes eye-tracking data obtained while patient watches curated videos; provides indicators of the presence or absence of ASD and indices that represent assessments of symptom severity

Sources: 21 CFR 882.1491, 2025 (www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-882/subpart-B/section-882.1491); FDA 510(k) Database, 2025 (www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm)

Establishing Special Controls

- New DMH diagnostic devices may require classification through the De Novo pathway
  - Limited number of authorized DMH diagnostic devices → novel devices may represent a new intended use
  - Technological characteristics of GenAI-enabled devices may sometimes introduce new or different risks that could which raise new questions of safety and effectiveness

- May require special controls to provide reasonable assurance of safety and effectiveness, which could include both premarket and postmarket requirements
  - Software validation and clinical performance testing prior to market authorization
  - Establishment of a postmarket performance management plan
  - Development and implementation of a risk management plan
  - Methods of effectively communicating benefits, risks, and appropriate use

Benefit Considerations for DMH Diagnostic Devices

- May enable and support remote monitoring and care
- May improve access to care
- May facilitate earlier or more timely assessment or diagnosis
- May broaden the types of information available to clinicians
- May provide specialized diagnostic support to general practitioners

Risk Considerations for DMH Diagnostic Devices

- Failures, incorrect analyses, lack of generalizability, or inaccuracies in measurements and calculations
- Use error, overreliance on, or misinterpretation of information

Resulting in

- Mis-evaluation of patient symptoms or status
- Mis-diagnosis of a patient's condition
- Delayed assessment or diagnosis of a patient's condition
- Inappropriate or ineffective treatment or management
- Missed or delayed identification of a crisis situation

Validation Considerations for DMH Diagnostic Devices

Type of validation data, and associated study design, depends on specific function and use

- Collecting physiological data or measuring symptom severity – accuracy and precision of the measurement; stability over repeated measurements
- Aiding in the diagnosis of a condition – understanding how the device would fit into existing methods of assessment and diagnosis; how will the information be interpreted in conjunction with other available information
- Monitoring or tracking symptoms associated with a condition – may provide longitudinal data demonstrating ability to accurately and reliably detect clinically meaningful changes in symptoms
- Providing predictive or prognostic information, such as estimating the likelihood or risk that a patient diagnosed with a substance use disorder relapses, or a patient diagnosed with major depressive disorder engages in self-injurious behavior within a certain about of time
- Facilitating adaptive therapy by automatically adjusting DMH therapeutic functions

Validation Considerations for DMH Diagnostic Devices

- Ensure the study design is aligned with the proposed intended use
  - Understand the level and nature of clinician involvement, including Rx vs OTC use
  - Define an appropriate method of determining clinical truth
  - Important to understand what the current alternative methods are for making related assessments to determine the meaningfulness of any newly proposed assessment

- Combination of assessment methods and inclusion of other physiological or patient data may improve diagnostic performance
  - Understanding of the basis for combining multiple sources of data
  - Understanding of the methods of training, development, and underlying data

Data Management and Transparency Considerations

- Data quality, integrity, and provenance
  - Varied sources and types of data, some not traditionally “medical”
- Transparency
  - Utilizing combinations of methods to communicate functionality, use of data, device benefits, risks, and appropriate use

Increasing DMH Diagnostic Device Autonomy Considerations

- Autonomous Diagnostics
  - Intended to provide diagnosis, not as an aid for clinical interpretation
  - Facilitates automatic and autonomous delivery of therapy; no human clinician involved prior to therapy
  - Rx vs OTC considerations

- Adaptive, Closed-loop Delivery
  - Instantaneous assessment of current symptom state with real-time updating of therapeutic content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