MEDICAL DEVICES FOR THE ASSESSMENT OF TRAUMATIC BRAIN INJURY

Traumatic Brain Injury Center of Excellence

WHAT IS A MEDICAL DEVICE?

The FDA defines a medical device as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article intended to diagnose, treat, or prevent disease.

WHAT ORGANIZATION IS RESPONSIBLE FOR REGULATING MEDICAL DEVICES?

The FDA Center for Devices and Radiological Health is the only U.S. organization that can regulate medical devices.

HOW ARE MEDICAL DEVICES CLASSIFIED?

- The FDA classifies medical devices on a three-tier system (Class I-III) based on:
  - The risk of injury or illness with use
  - How the device is intended to be used
  - Indications for using the device

Class III

- **High-risk devices**
- **FDA-approved devices**
- Subject to pre-market approval and general controls

Class II

- **Moderate-risk devices**
- **FDA-cleared devices**
- Most devices to aid in the assessment of TBI
- Subject to general and special controls (if indicated)

Class I

- **Low-risk devices**
- Subject to general controls
- May be exempt from premarket 510(k) notification

WHAT IS THE DIFFERENCE BETWEEN GENERAL AND SPECIAL CONTROLS?

- **General controls** are basic provisions that give the FDA means for ensuring device safety and effectiveness.
- **Special controls** are device specific and are used when general controls do not provide sufficient mitigation of risk.

Disclaimer: Research is still emerging on the safety and effectiveness of TBI-related devices. TBICoE and the Defense Health Agency **do not endorse or discourage** the use of any device. Clinicians, leaders, and researchers should use evidence-based research and **follow FDA guidance** when choosing medical devices for clinical or operational use.

Released February 2024 | Revised January 2025 by the Traumatic Brain Injury Center of Excellence
This product is reviewed annually and is current until superseded. **800-870-9244** • Health.mil/TBICoE

DHA Defense Health Agency ®

WHAT ARE THE FDA REGULATORY PATHWAYS FOR MEDICAL DEVICES?

Most TBI relevant devices intended to be marketed for public use go through one of three regulatory pathways depending on the novelty of the device:

Pre-Market Approval (PMA)

- Most rigorous pathway
- Requires extensive clinical evidence on the safety and effectiveness of the device
- For high-risk devices
- Devices considered APPROVED
- Submission number starts with a "P"

Pre-Market Notification (510k)

- Does not require PMA, but may require clinical data to demonstrate substantial equivalence to existing device(s) on the market
- For moderate- and low-risk devices
- Devices considered CLEARED
- Submission number starts with a "K"

De Novo

- For new devices where there is no comparable device on the market
- Devices are classified Class I or II, and can serve as a predicate for future device submissions
- Devices are GRANTED
- Submission number starts with a "DEN"

Note: All devices are registered and listed through the FDA. Additional regulatory pathways exist for devices used only in premarket research or for rare medical conditions. Devices that do not have an FDA decision letter on clearance or approval may be used in the research setting but should not be used to inform clinical decision-making.

THE 13 FDA-CLEARED DEVICES FOR ASSESSING TBI

To date, 13 devices are indicated by the FDA to aid in the assessment of a suspected head injury. These devices are not intended for use as a standalone method to diagnose TBI and should only be used as supplementary tools alongside routine clinical evaluations.

Device	Type of Device
Automated Neuropsychological Assessment Metrics (ANAM)	Computerized neurocognitive assessment
Immediate Post-concussion Assessment and Cognitive Testing (ImPACT)	Computerized neurocognitive assessment
DANA	Computerized neurocognitive assessment
EyeBOX	Eye tracking
Eye-SYNC	Eye tracking
Banyan Brain Trauma Indicator	Blood-based biomarkers
i-STAT TBI Plasma Test	Blood-based biomarkers
i-STAT TBI Whole Blood Test	Blood-based biomarkers
TBI Test with the Alinity I System	Blood-based biomarkers
TBI Test with the Architect i1000SR System	Blood-based biomarkers
VIDAS TBI	Blood-based biomarkers
BrainScope TBI	Electrophysiology (EEG)
Infrascanner 2000 & 2500	Near-infrared spectroscopy

Other devices are in development or are on the market for clinical or research use but are not yet FDA cleared or approved. Further research is needed to determine their clinical and operational utility.

CONSIDERATIONS FOR CLINICIANS AND RESEARCHERS BEFORE USING A DEVICE

- Is there a standard device or assessment with the same intended purpose?
- What is the sensitivity and specificity of the device?
- How long does it take to complete an assessment of TBI with this device?
- Is the device feasible and safe to use?
- What is the optimal setting for using the device (i.e., point of injury or point of care, research or laboratory, deployed or austere environment)?
- Has the device displayed optimal functioning in the intended setting for use?
- Does the device require other technology or assessments to function properly?

Do you have questions about this fact sheet? Feedback? Email us at dha.TBICoEinfo@health.mil.