

# MEDICAL DEVICES FOR ASSESSMENT OF TRAUMATIC BRAIN INJURY

Traumatic Brain Injury Center of Excellence

## WHAT IS A MEDICAL DEVICE?

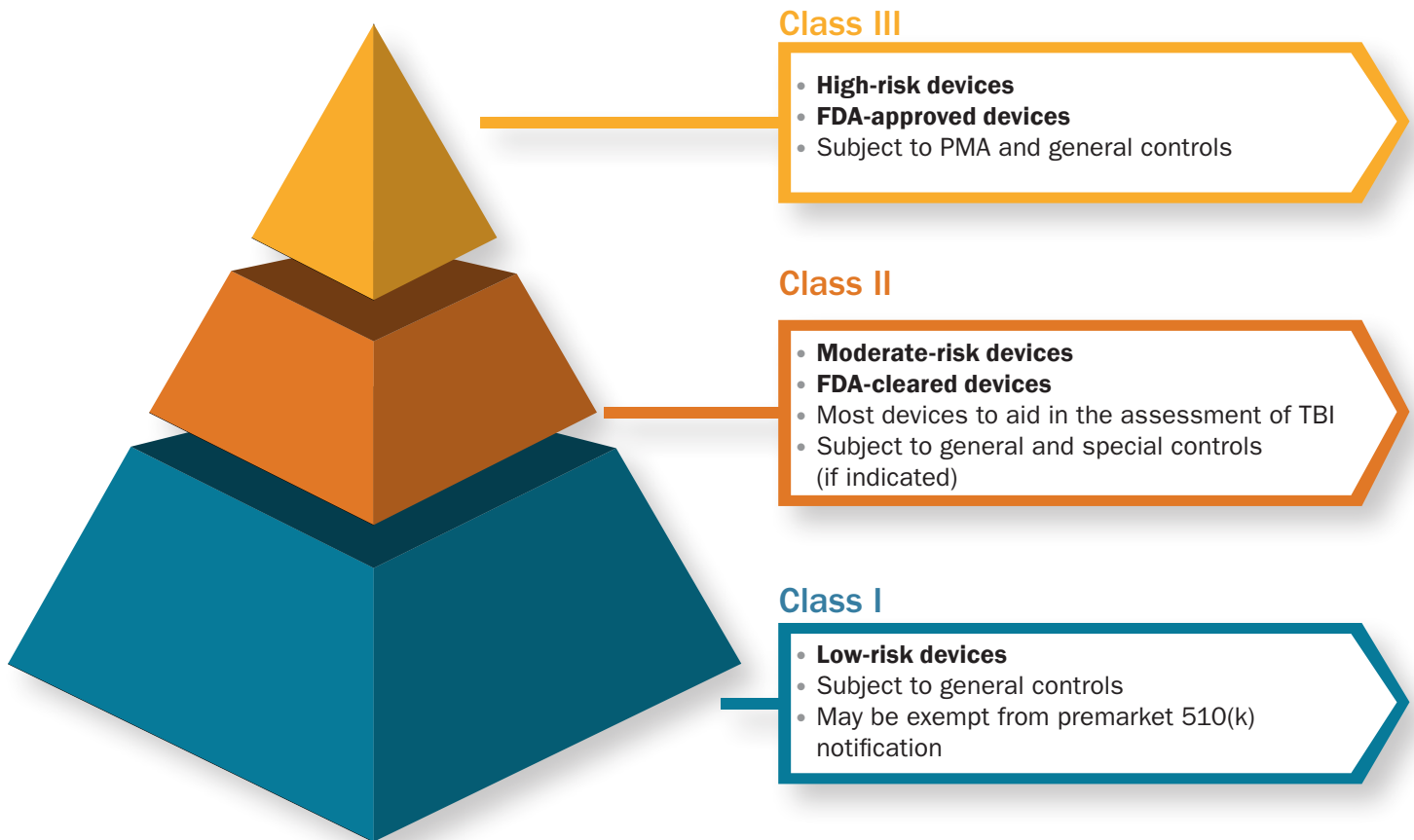
The Food and Drug Administration defines a medical device as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article intended to diagnose, treat, or prevent disease.

## 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
  - Indication(s) for use of the device
- **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.

## WHAT ARE THE FDA REGULATORY PATHWAYS FOR MEDICAL DEVICES?

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

### Pre-Market Approval (PMA)

- Most rigorous pathway
- Requires scientific evidence that the safety and effectiveness of the device outweigh the risk
- Devices considered APPROVED
- Submission number starts with a “P”

**Note:** Additional regulatory pathways exist for devices used only in premarket research or for rare medical conditions.

### Pre-Market Notification (510k)

- For products that are substantially equivalent to an existing device on the market
- Does not require PMA, but may require clinical data to demonstrate substantial equivalence to existing device(s)
- Devices considered CLEARED
- Submission number starts with a “K”

### De Novo

- For new devices where there is no comparable device
- Devices classified Class I or II
- De Novo devices can serve as a predicate for future devices
- Devices are GRANTED
- Submission number starts with a “DEN”

## WHAT IS THE DIFFERENCE BETWEEN CLEARED, APPROVED, AND REGISTERED DEVICES?



**FDA CLEARED** devices have undergone 510(k)



**FDA APPROVED** devices have undergone PMA regulation



All devices are **REGISTERED** and **LISTED** through the FDA

**Note:** 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 EIGHT FDA-CLEARED DEVICES FOR ASSESSING TBI

To date, only eight devices are indicated by the FDA to aid in the assessment of a suspected head injury (TBI). These devices are not intended for use as standalone methods 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
EyeBOX	Eye tracking
Eye-SYNC	Eye tracking
Banyan Brain Trauma Indicator (BTI)	Blood-based biomarkers
i-STAT TBI Plasma Test	Blood-based biomarkers
BrainScope TBI	Electrophysiology (EEG)
InfraScanner 2000	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 [dha.TBICoEinfo@health.mil](mailto:dha.TBICoEinfo@health.mil).