#PEAC2022

Augmented Reality (AR) and Virtual Reality (VR) Medical Devices

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AUGMENTED REALITY (AR) AND VIRTUAL REALITY (VR) MEDICAL DEVICES

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Overview

- The Technology
  - Definitions
  - Applications and Benefits
  - Concerns and Risks
- The Regulatory Paradigm
  - Premarket
  - Postmarket
  - Special Considerations in AR/VR
- Summary

What is AR and VR?

Virtual Reality:

Virtual world experience that may require a headset to completely replace a user's surrounding view with a simulated, immersive, and interactive virtual environment

Augmented Reality:

Real-world augmented experience with overlaying or mixing simulated digital imagery with the real world as seen through a camera or display, such as a smartphone or head-mounted or heads-up display (HUD). Digital imagery may be able to interact with real surroundings (often controlled by users)

Applications and Benefits

AR/VR technologies are already in use by health care providers, patients & caregivers

- Mental health
- Neurological disorders
- Diagnosing and treating pediatric conditions

- Pre-operative planning
- Surgical support
- Non-pharmacological adjuncts to managing pain

Concerns and Risks

- Cybersickness
- Collisions and falls
- Other discomfort and injury
  - Fatigue, eye strain, headaches, mismatch between self and digital world
- Privacy violations
- Habitual usage
- Seizures
- Inequities

Populations with Special Concerns

The patient voice is key to understanding the benefits and risk factors related to using AR/VR technology.

- Pediatric Patients
- Cognitively Impaired Patients
- Mental Health Patients
- Patients Undergoing Surgery
- Socioeconomically Vulnerable Patients

Premarket Submissions to FDA

Regulatory Pathway

- **510(k)**

  Certain existing devices may be able to add AR/VR as a capability by demonstrating "substantial equivalence"

- **De Novo Request**

  Provide robust data so FDA can determine that general and special controls (i.e., certain legal requirements) provide "reasonable assurance of safety and effectiveness"

Requirements

- Bench performance testing with the device
  - Electrical safety testing, software review, etc.
- Clinical performance testing with the device
- High-quality real-world evidence with the device
- Human factors/usability testing

Labeling

- Information provided to help users (patients or caregivers or healthcare professionals) understand how to use a device safely and correctly
- Labeling can include training information on how to use the device
- Labeling can inform users of benefits and risks
- Labeling can help mitigate the risks of device use

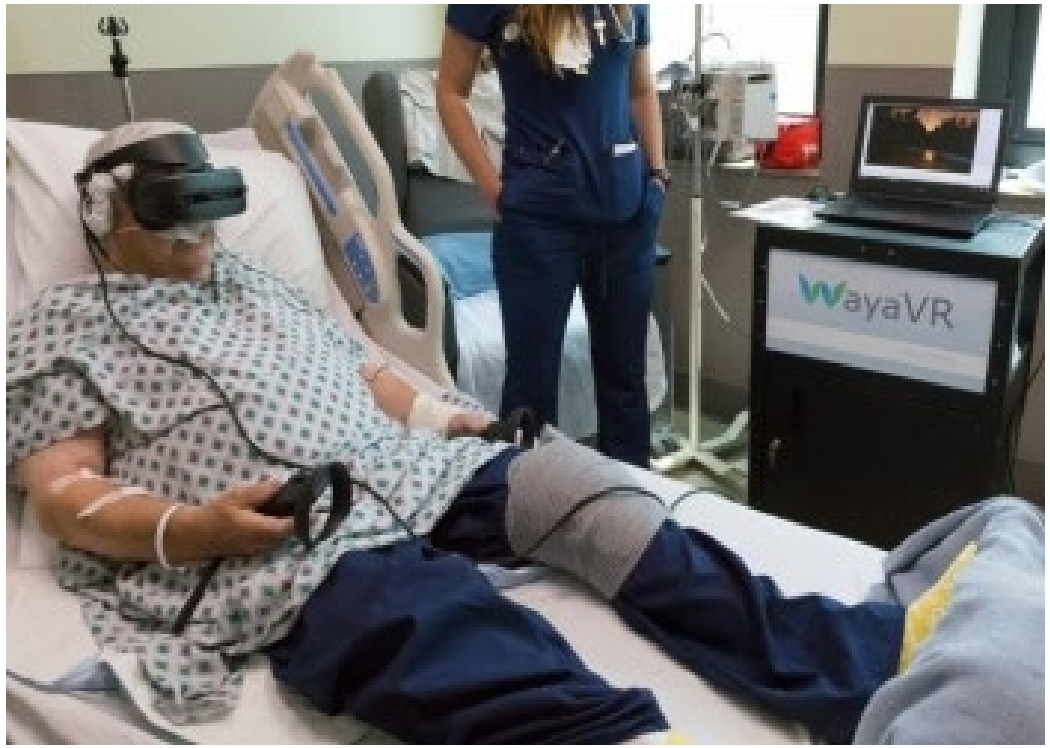
Postmarket Surveillance

- Medical Device Reporting (MDR)
  - Mandatory reports
  - MedWatch
    - Voluntary reports
  - Medical Product Safety Network
    - Hospital-based reports (MedSun)
- Postmarket surveillance studies
  - Post-approval studies
  - 522 studies
- National Evaluation System for Health Technologies (NEST)

Special Considerations for AR/VR Devices

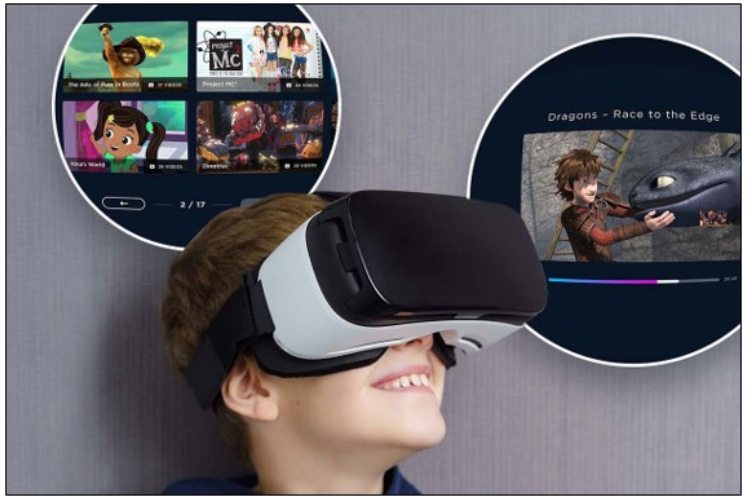
FDA may assess the impact of special factors particularly relevant to AR/VR safety and effectiveness.

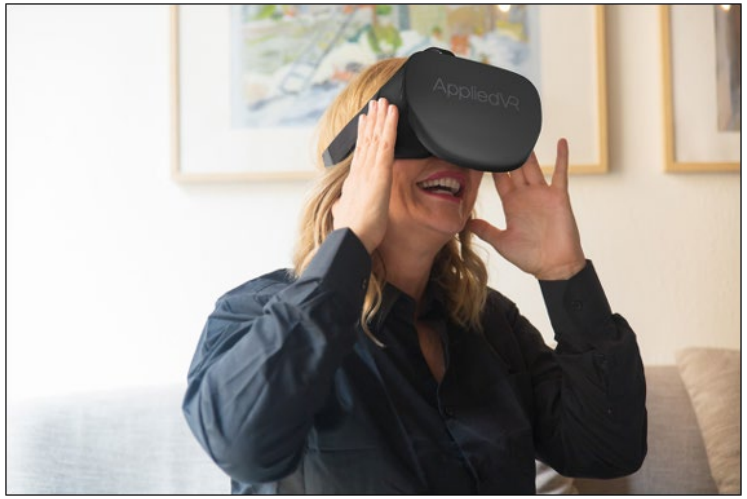
- Off the shelf devices
- Age/decision making capacity
- Informed consent
- Uncertainty
- Access
- Labeling



Courtesy of VA.gov

Summary





Thank You!

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