NIH Workshop on Standards and Modularity of Brain-Computer Interfaces and Neuroprostheses: A FDA Staff Perspective

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Recent History

• FDA Public Workshop - Brain-Computer Interface Devices for Patients with Paralysis and Amputation, November 21, 2014
  – Present and discuss our risk-based classification system
  – Discuss challenges in the development of BCI devices

• BCI Position Paper Considerations:
  – Patient populations, metrics, and modularity

• FDA Draft Guidance (still under development)

• Current Workshop-Evaluate new research and Standards that may further advance field
Agenda

1. FDA Medical Device Classification System
2. Approved and cleared BCI devices
3. BCI Components
4. FDA Review Considerations
5. Standards
6. FDA Guidance Document development
FDA’s Medical Device Classification System

A NEW MEDICAL DEVICE

B

CLASS I
low risk

CLASS II
moderate/controlled risk

CLASS III
high risk

C

exceeds limits of exemption

< 4000 patients per year in U.S.

D

510(k)
substantially equivalent to predicate?

de novo
510(k) no predicate

HDE
probable benefit outweighs risk

PMA
reasonable assurance of safety and efficacy

E

CLEARANCE TO MARKET DEVICE

APPROVAL TO MARKET DEVICE

A Few Examples of FDA Cleared/Approved BCI devices

- **Assistive Technology:**
  - DEKA Arm System ([DEN120016](#), Product code PAE)
  - Ottobock Dynamic Arm ([K123795](#), product code GXY, IQZ)

- **Full Implanted System:**
  - Freehand System ([P950035](#):
A Few Examples of FDA Cleared/Approved BCI devices

• Signal Acquisition:
  – Cortical Electrodes (*intended for temporary, less than 30 days, recording and monitoring of brain electrical activity*)
    • Blackrock Microsystems NeuroPort Cortical Microelectrode Array System (**K110010**, product code GZL)
    • Cyberkinetics NeuroPort Electrode (**K070272**, product code GZL)
  – Intraoperative Cortical Electrodes (*intended for temporary placement on the surface of the brain for stimulation the brain and recording the brain’s electrical activity*)
    • Blackrock Cervello Stim (K151354, product code GYC)
Components of a BCI System

Signal Acquisition and Stimulation
- Cutaneous Electrodes
- Implanted Muscle Electrodes
- Implanted Nerve Electrodes

Software – Signal Processing and Control
- Signal Generator
- Signal Processor
- Controller

Assistive Device
- Prosthetic Limb
- Sensory Feedback
- Degrees of Freedom
A Few Examples of FDA Review Considerations

Regulatory Considerations

- System vs. Component Testing
  - EMG controlled prosthetic arms are cleared as systems
- Single fault in one component can impact the system as a whole
- System performance when one component is modified
- Either “approve” a component for use with devices that are not yet legally marketed after the approval of a full system or only approve a full system

Performance Testing Considerations

- Non-clinical considerations:
  - Electromagnetic compatibility
  - Electrical safety
  - System level integration should also be considered at the software level
- Clinical considerations:
  - Unintended stimulation or movement
  - Lack of stimulation at a critical point in device use

*Master files – may be used to help address our regulatory review
Other Devices Cleared/Approved as Components

- Implantable Cardioverter/Defibrillators
- Programmers
- Cardiac Leads
- Cutaneous electrodes
NIH Research Funding and NIST Standards

• Cross-cutting standards for technology
  – ISO 14708-1: 2000 Implants for surgery – Active implantable medical devices – Part 1: General requirements for safety, marking and for information to be provided by the manufacturing.

• Additional standards to help BCI devices?
FDA Guidance Document Development

• Draft Guidance Documents (*Underdevelopment for BCI*)

• Comment period – 90 days from the publication in the Federal Register

• FDA Position Paper Now Available
Medical Device Review Contact Information

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