



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

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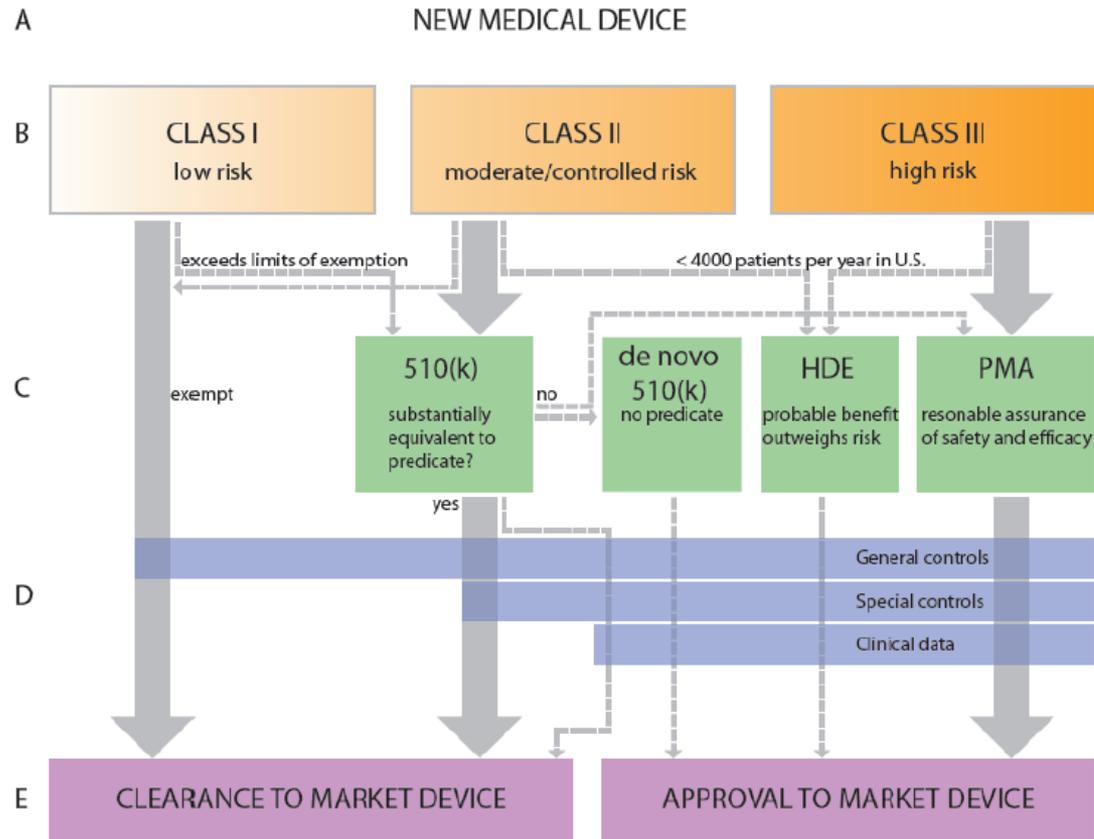
Recent History

- 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- FDA Draft Guidance (still under development)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



*Ref: Welle C., Krauthamer, V. (2012) FDA Regulation of invasive neural recording electrodes: a daunting task for medical innovators. *IEEE Pulse* 3(2); 37-41.

A Few Examples of FDA Cleared/Approved BCI devices

- **Assistive Technology:**

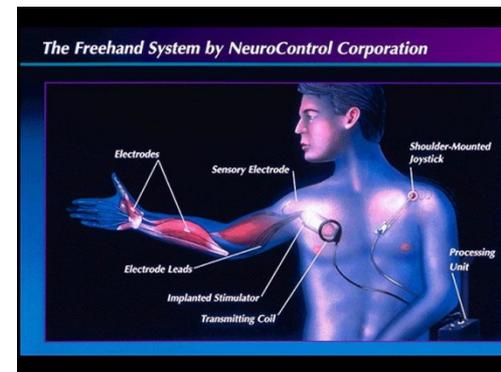
- DEKA Arm System ([DEN120016](#), Product code PAE)



- Ottobock Dynamic Arm ([K123795](#), product code GXY, IQZ)

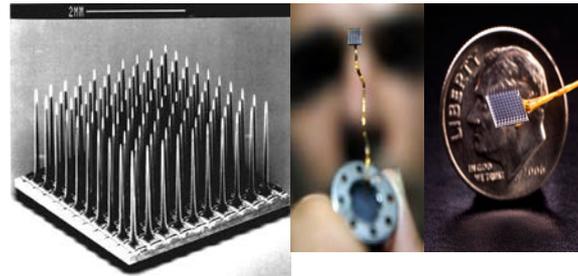
- **Full Implanted System:**

- Freehand System ([P950035](#)):

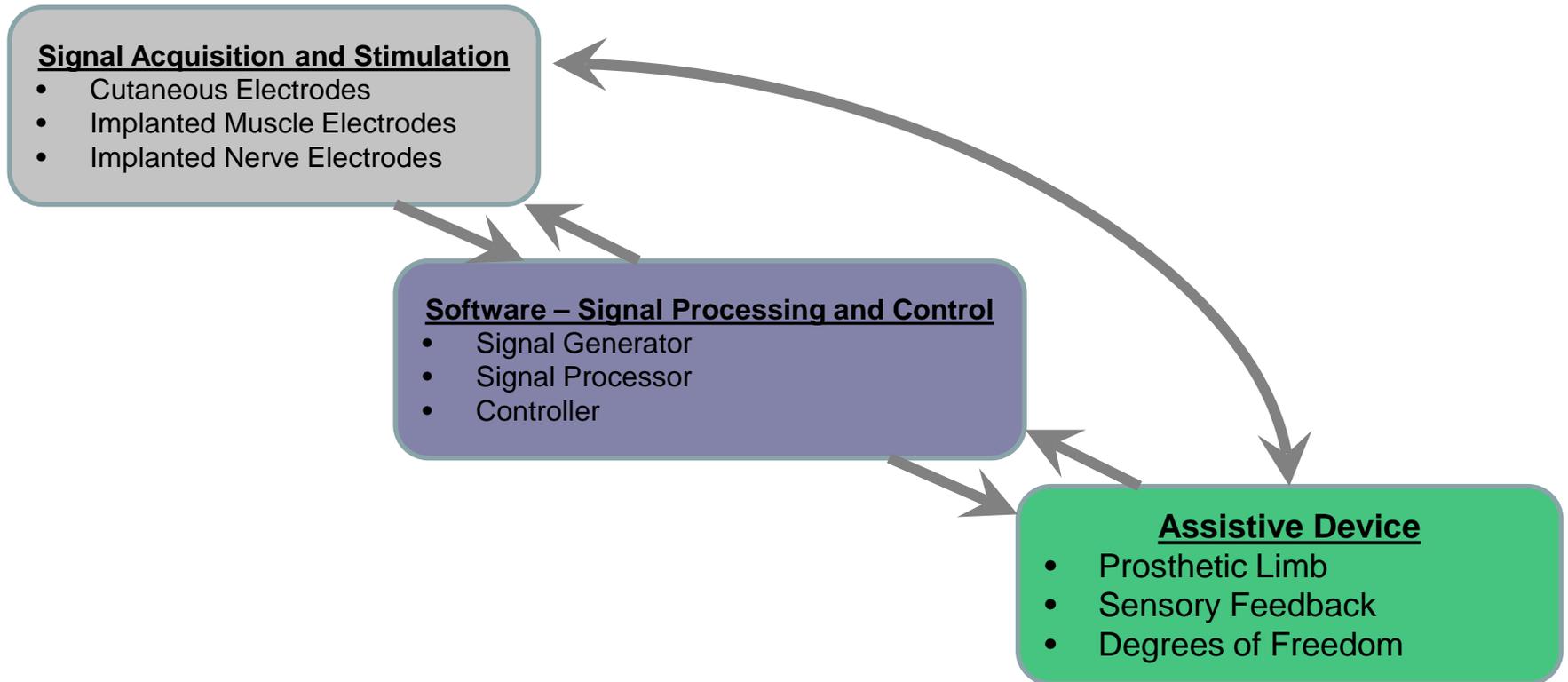


A Few Examples of FDA Cleared/Approved BCI devices

- 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



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 a full system or only approve a full systems

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 14708-3: 2008 Implants for Surgery – Active Implantable Medical Devices – Part 3: Implantable neurostimulators
 - 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.
 - IEC 60601-1-2:2007 Medical Electrical Equipment – Part 1-2 General requirement for basic safety and essential performance – collateral standard: Electromagnetic compatibility – requirements and tests
 - IEC 60601-1 (3rd Edition) Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
 - ISO 10993-1: 2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within Risk Management Process
- **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
 - Bowsher, K. et al. (2016). Brain–computer interface devices for patients with paralysis and amputation: a meeting report. *Journal of Neural Engineering*. Volume 13(2).



Medical Device Review Contact Information

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Pre-submission Pathway – Guidance Document “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff” - <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf>

Acknowledgements

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