DRAFT FDA Guidance Document on Implanted Brain Computer Interface (BCI) Devices for Patients with Paralysis or Amputation – Non-clinical Testing and Clinical Considerations

Graz Brain-Computer Interface Conference, Workshop 3: Standards for Neurotechnologies and Brain-Machine Interfacing
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Office of Neurological and Physical Medicine Devices (OHT5)
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration (FDA)
Objectives

• Provide the history of the DRAFT Implanted BCI guidance document

• Provide a brief overview of the DRAFT Implanted BCI guidance document sections

• Provide a brief overview of:
  – The FDA Guidance Documents
  – The FDA and Standards
History of DRAFT Implanted BCI Guidance

- Public Workshop - Brain-Computer Interface Devices for Patients with Paralysis and Amputation, November 21, 2014
- NIH Workshop on Standards and Modularity of Brain-Computer Interfaces and Neuroprostheses, June 30, 2016
- Draft Implanted BCI Guidance Document posted, February 25, 2019
- Commenting period open for 60 Days, ended April 26, 2019
Scope of the DRAFT Implanted BCI Guidance

Implanted BCI Devices – “neuroprostheses that interface with the central or peripheral nervous system to restore lost motor and/or sensory capabilities in patients with paralysis or amputation”

– Leap-Frog Guidance
– Neural Interface
  • “Central or peripheral nervous system”
– Intended use/Function
  • “restore lost motor and/or sensory capabilities”
– Indications for Use/Patient Population
  • “Patients with paralysis or amputation”
– Submission Types
  • Q-submissions
  • Investigational Device Exemptions
    – Early Feasibility Studies
    – Pivotal Studies
# Sections of the DRAFT Implanted BCI Guidance

## Overview of Recommendations

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Future Steps for the DRAFT Implanted BCI Guidance

- Review of Comments and Revise, if applicable
- Finalization of the Implant BCI Guidance Document
FDA Guidance Documents

• Documents prepared for FDA staff, regulated industry, and the public
• Describe the agency’s interpretation of or policy on a regulatory issue
• **DO NOT** create or confer any rights for or on any person and do not operate to bind FDA or the public
• Alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulation, or both
FDA and Standards

• Standards are documents, established by consensus that provides rules, guidelines or characteristics for activities or their results.¹

• Through the Food and Drug Administration Modernization Act of 1997, which modified Section 514(c) of the Medical Device Amendment of 1976, FDA can:
  – Formally recognize consensus standards and to accept a declaration of conformity to a recognized standard

• FDA Uses of standards:
  – Recognize by reference in part or whole
  – Use both national and international standards
  – Can promote international harmonization
  – Reference standards in published guidance documents
  – Encourage conformance to standards to streamline regulatory review and fosters quality
  – Conformance is voluntary, unless a standard is incorporated by reference into regulation

¹ https://www.ansi.org/about_ansi/faqs/faqs?menuid=1
Additional Information Available

- CDRH Learn:  
  http://www.fda.gov/Training/CDRHLearn/
- CDRH Device Advice:  
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/
- Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices Guidance Document:  
  https://www.fda.gov/media/71983/download
- Standards and Conformity Assessment Program:  
- CDRHstandardsstaff@fda.hhs.gov
- Guidance Documents (Medical Devices and Radiation-Emitting Products):  
- Q-submission Guidance Document:  
Thank You!

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