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Example - Early Feasibility Investigational Device Exemption

IDE Section:

Introductory “Read Me” Document

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Important notes regarding the COSMIIC presentation of an example filing for an early feasibility investigational device exemption (EFS IDE).

- The example documents provided represent the complete IDE filing for an EFS IDE that received a modified conditional approval in 2014, and subsequent full approval in 2015, following the submission of additional information in response to FDA questions.
- This example IDE describes the state of the technology at the time of submission and the state of the investigational plan at that time, both of which have undergone modifications since then.
- All text is verbatim except for highlighted text. Highlighted text is included to provide context to the IDE and justification for redactions.
- Redactions were made for material that is no longer relevant and/or materials containing privacy concerns, including names, addresses, and proprietary information.
- Note that components of the COSMIIC System are referred to as the "Networked Neuroprosthesis". This older terminology was left in place as originally written.
- Some descriptions of the Networked Neuroprosthesis may not accurately describe the current version of the COSMIIC System. Please refer to technology documentation updates via cosmiic.org for the most up-to-date descriptions.
- Sections 9 and 10 of the submission have been left out. These sections contain private information. The contents of these sections can be determined by reviewing the requirements for IDEs as presented by the FDA.
- This IDE is an example for how the COSMIIC System can be applied and communicated for a targeted function—hand grasp in spinal cord injury. IDE submissions for future applications of the COSMIIC system must differ from the original IDE submission on a case-by-case basis considering application, patient population, and technology updates.
- All testing was done to standards relevant in 2014, all new IDE submissions will need to be compliant to current standards.
- For full guidance on the required and recommended contents of an IDE, please review FDA guidance on the topic.
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