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## Example - Early Feasibility Investigational Device Exemption

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### IDE Section:

Cover Letter and Table of Contents

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November 10, 2014

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993-0002

RE: Original IDE Application, "Early Feasibility Study of the Networked Neuroprosthesis for Grasp and Trunk Function in Spinal Cord Injury"; Sponsor Investigator: [REDACTED], Ph.D.

To Whom It May Concern:

[REDACTED] a Sponsor/Investigator at Case Western Reserve University, is submitting this Investigational Device Exemption (IDE) Application to request permission to initiate a clinical evaluation of the Networked Neuroprosthetic (NNP) System to provide grasp and trunk function for individuals with cervical level spinal cord injury. This application is part of the FDA Early Feasibility Study Pilot Program. **Our EFS IDE pre-IDE number is I111144.**

[REDACTED] with collaborating investigators [REDACTED] are seeking permission to implant **up to 10 patients at a single investigational site,** [REDACTED]. The primary objective of this study is to assess the feasibility of providing improved grasp and trunk function for individuals with cervical level spinal cord injury. Results of this study will inform the design of a future multi-center clinical trial.

If you have any questions or require additional information, please contact [REDACTED] or [REDACTED] at the contact information on the following page.

**The eCopy is an exact duplicate of the paper copy.**

Sincerely,

[REDACTED]

[REDACTED]

Enclosure

**Manufacturer:**

Case Western Reserve University  
2040 Adelbert Rd.  
Cleveland, Ohio 44106

**Sponsor/Investigator:**

[REDACTED]

**Contact for Administrative Questions:**

[REDACTED]

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