Month XY, 20XY

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center – WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Attn: *Jane Doe*, MD

Director, Division of Something

**RE: Original Application for Investigational Device Exemption**

Dear *Dr. Doe*:

Please find enclosed an electronic copy, on CD, of this original application for an Investigational Device Exemption (IDE).

*Device Name* is an investigational device that will be used in *Insert Intended Use Here.* I will serve as the sponsor for this IDE and the initial study protocol for use under this IDE is entitled “*A Phase I Trial of Device in Humans*”. The device is manufactured by *Insert Name and Address of Manufacturer Here*. *Manufacturer Contact Person* can be contacted at *Telephone Number* or by facsimile at *Fax Number*.

The FDA has previously provided guidance on the development of this device in the form of a Pre-Submission meeting. A copy of the meeting minutes has been provided in section *Y* of this IDE application. The following files are referenced within this IDE application: *MAFXXXXX*

If there are any questions regarding this submission, please contact myself or Jacob Durham, at (919) 668-xxxx or jdurham@notes.duke.edu. Mr. Durham is authorized to communicate with the FDA on any issue relating to this IDE application.

Sincerely,

John Doe, MD

Professor, Department of Something

Duke University

Phone: 919-684-XXXX

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Email: john.doe@duke.edu