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*

CDRH, Division of Something

**RE: IDE GXXXXXX/Supplement 00# (or Report 00# or Amendment 00# to Supplement/Report 00#)**

**Progress Report, New Protocol, Change in Protocol, Unanticipated Adverse Device Effect, etc…**

Dear *Dr. Doe*:

*Sample cover letter language is provided below for IDE maintenance submissions. Common IDE maintenance submission types are included as a reference, but the list is not exhaustive. You should modify the language based on the contents of the submission. Remove all language that is not applicable.*

Please find enclosed one eCopy, on CD, of [Supplement/Report] 00# to IDE GXXXXXX.

*Change in Protocol*

This Supplement is a protocol amendment for the study titled "TITLE".

This protocol amendment incorporates the following changes:

a) Change #1; see section # and throughout document,

b) Change #2; see section ##,

c) Changes in statistical analyses and sample size due to the change #1; see section ###, and

d) Various minor corrections and clarifications throughout the document.

Included in this supplement are:

1. A change table describing the major changes to the protocol with rationale

2. Protocol v##

3. Protocol, red line comparing the current version (v#) against the new version (v##)

*Current Investigator List*

This Report is a current investigator list for the study titled "TITLE".

*Progress Report*

This Report is the ## progress report for the study titled "TITLE".

Also, per §812.150(b)(4) we are submitting a current investigator list. This list of ## active sites is incorporated into the progress report as Table X.

*Amendment to a Progress Report*

This Amendment to Report XXX is our response to the agency's request for additional information regarding protocol deviations provided in our recent progress report for the study titled "TITLE".

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

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