Month XX, 201X

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: **Initial IDE Application**

Dear Dr. [Division Director]:

Per 21 CFR 812.20, please find enclosed three copies of this initial application for a Sponsor-Investigator IDE. We propose to evaluate [name of investigational device] under this IDE for [safety] [efficacy] for the [treatment] [diagnosis] of [disease or condition].

This submission also contains the initial study protocol [*Study Number*] *Protocol* *v. 1.0* entitled, “A Multi-center, Randomized Study of the Effects of [Device] on [Condition] in [Disease].”

If you have any questions regarding this submission, please contact myself or [Name of Sub-Investigator, MD] at [phone number] or [email address]. Dr. [Name of Sub-Investigator] can act on my behalf on any issue relating to this IDE.

Sincerely,

[Sponsor Name], MD

Title

Institution

Phone number

Email address

cc: file

submitted in triplicate: *Application for an Investigational Device Exemption*

[*Study Number*] *Protocol* *v. 1.0*