***Please use UA letterhead issued by your own department.***

*Month DD, YYYY*

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:**  *Name*, MD

*Title*, Division of *[Therapeutic Area]*

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

Dear *Name*:

Please find enclosed three copies of this initial Investigational Device Exemption (IDE) application for the clinical feasibility study entitled, *[title]*, and an enclosed electronic copy, on CD, of this original application for IDE.

**Device Information**:

Device Name: *Name*

Intended Use: *Device Name* is an investigational device that will be used in *[explain intended use here]*.

*Device Name* Structure and Function: *[describe briefly]*.

**Sponsor Contact Information:**

The initial study protocol for use under this IDE is sponsored by the University of Arizona.

The Sponsor/Principle Investigator:

*Name, Title*

*Center, Department*

University of Arizona

*Phone*

*Fax*

*Email*

**Contract Manufacturer Information:**

*Contact Name*

*Contract Manufacturer Name*

*Address*

*Phone, Fax, Email*

**Applicant Information:**

*Name, M.D., M.P.H., Ph.D.*

*Title*

*Center*

*College*

*University of Arizona*

*Address*

*Phone*

*Fax*

*E-mail*

**Prior Meetings:**

There were no prior pre-IDE meetings with the reviewing division. We reaffirm that this study will not proceed until this IDE is effective and IRB approval is received from *[enter IRB of record]*. The information in this IDE is confidential to University of Arizona.

If there are any questions regarding this submission, please contact myself or *[name of sub-investigator or other contact]* at *[phone number]* or *[email address]. [Name of Sub-Investigator or other contact]* can act on my behalf on any issue relating to this IDE.

Sincerely,

*Name, Title*

*College*

University of Arizona