**IDE APPLICATION TEMPLATE:**

**COVER LETTER FOR ORIGINAL IDE APPLICATION**

**On Letterhead**

*Date*

For: Devices regulated by the Center for Devices and Radiological Health (CDRH):

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

For: Devices regulated by the Center for Biologics Evaluation and Research (CBER):

Center for Biologics Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Telephone Number: 240-402-8010 or 1-800-835-4709
Email: industry.biologics@fda.gov

**Re.: Original IDE Application**

Dear FDA Staff:

The information being provided in the attachment constitutes an **original** sponsor-investigator IDE application.

**Device Information:**

**Device name**: *Specify the name of the device under investigation*

**Intended use of device***: Specify the intended use of the investigational device; i.e., as per the objective(s) of the planned clinical investigation.*

**Sponsor-Investigator Contact Information:**

*Sponsor-investigator name and degree(s)*

*Academic department or division affiliation*

University of California, Los Angeles

*Address*

*Telephone number*

*Fax*

*Email address*

**Manufacturer Information:**

*Name of device manufacturer*

*Address*

*Contact person*

*Telephone number*

*Fax*

*Website (if available)*

**Additional Information:**

**Q-Submission/Pre-Submission Meetings**:

*Describe any discussions with the FDA reviewing division regarding this device. If a Q-submission (Pre-IDE) document was submitted, indicate the Q-Submission/Pre-Submission number assigned and the name of the FDA reviewer, if known. If a Q-Submission/Pre-Submission meeting occurred, provide the name of the FDA contact person and a copy of the meeting minutes. If there was no Q-Submission/Pre-Submission document submitted or meeting, indicate such.*

**Waiver Requests/Justification**:

*Identify any requests for waivers and include a justification for the waiver. If no waivers are being requested, indicate such.*

**Referenced Files**:

*Identify any files that are referenced in the IDE application, such as an existing Premarket Approval, Premarket Notification 510(k), IDE, or device master file. If such files were not submitted by the sponsor-investigator, include a letter from the owner of the files that grants FDA permission to reference the file in its review of this IDE application. If there are no referenced files, indicate such.*

Please accept my thanks, in advance, for the FDA’s review and consideration of this original IDE application.

If you require additional information, please contact me at the phone number or email address provided below *or [Name] who may act on my behalf at [email address] or [phone number]*.

Per FDA guidance, this request is being submitted via the CDRH Customer Collaboration Portal.

Sincerely,

*Typed name of sponsor-investigator*

*Telephone number*

*Email address*

**Attachments**:

1. *List attachments*