*Date*

Food and Drug Administration

Center for Devices and Radiological Health

Document Mail Center

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WO66-G609

Silver Spring, Maryland 20993

**Sponsor-Investigator Contact Information:**

*Sponsor-investigator name and degree(s)*

*Academic department or division affiliation*

University of Pittsburgh

Hieber Building, Suite 401

3500 Fifth Avenue

Pittsburgh, PA 15213

Telephone number:

Email address:

FAX number:

**Q-Sub Type.** Pre-sub

**Purpose.** *Include the overall purpose of the Q-Sub including goals for the outcome of the interaction with FDA.*

**Device or Product Description.** *Provide an explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device. A brief description of the manufacturing process should be included if the manufacturing process may affect safety and/or effectiveness and, may therefore, impact FDA’s recommendations regarding device testing. The generic name of the device as well as any proprietary name or trade name should be included. Images, videos, and more detailed information may be included as appropriate in the submission itself.*

**Proposed Indications for Use or Intended Use.** *Include a description of the disease(s) or condition(s) the device will diagnose, treat, prevent, cure or mitigate, and a description of the patient population for which the device is intended.*

**Regulatory History.** *Provide any relevant previous communications with FDA about the subject device including but not limited to any marketing submission, IDE, 513(g), and/or Q-Sub application numbers relevant to the subject Q-Sub. The submission should also include a brief summary of these previous FDA interactions and submissions (and submission number(s)), including feedback received and resolution of that feedback (or justification of alternative paths) as applicable.*

Dear Division Director,

I am writing to request a Pre-submission meeting for the purpose described above. The proposed clinical protocol is included for review.

**Planned Follow-On Submission.** A future IDE submission is the focus of our Pre-Sub questions.

**Background Information.** *Include sufficient background information and supporting documents to allow FDA to develop feedback for the Pre-Sub questions you pose. This information might include literature articles, full device description with engineering drawings, proposed labeling, videos, and/or red-lined protocol revisions depending on the specific questions for which you are requesting feedback.*

*While the importance of a complete background package cannot be overstated, it should also be noted that submission of extraneous information can be counterproductive. We recommend that you keep your submission targeted and focused.*

**Specific Questions.** *A Pre-Sub should include clear, specific questions regarding review issues relevant to a planned IDE, IND, CW, Accessory Classification Request, or marketing submission (e.g., questions regarding non-clinical and clinical testing protocols or data needed to support the submission) to allow FDA and the submitter to focus their efforts on issues most relevant to moving a project forward. You may wish to describe your perspective on the questions you provide FDA to inform FDA’s review.*

The information below is included to facilitate scheduling:

1. A draft agenda *(the proposed topics to be presented and the estimated time for each agenda item, to the extent possible pending FDA feedback);*
2. Meeting format *(i.e., written feedback only, teleconference, or in person);*
3. *Three (3) or more preferred dates and times when you are available to meet. While you should propose dates that suit your schedule, please keep in mind that FDA needs sufficient time to review the material submitted, hold internal discussions if needed, and identify a meeting time when the necessary team members are available. NOTE: If your proposed dates do not allow for adequate preparation, FDA may not be able to accommodate your requested dates and will offer you alternative dates within an appropriate timeframe. Please refer to the specific timelines for each type of meeting request when considering proposed dates that are likely to be accepted by FDA.*
4. *The planned attendees, including each attendee’s position, or title, and affiliation.*
5. *If you have not yet identified all your attendees, you should indicate the type of subject matter experts you plan to invite.*
6. *FDA recommends that submitters identify in their cover letter any appropriate FDA staff that are requested to attend the meeting if specific expertise may be needed (e.g., staff from other Centers).*

Please feel free to contact me directly at *(insert phone)* or by e-mail *(insert e-mail)* if you would like to discuss this request.

Respectfully,

*Principal Investigator’s name*

*Principal Investigator’s academic department*

University of Pittsburgh

3500 Fifth Avenue, Suite 401

Pittsburgh, PA 15213