*Date*

Food and Drug Administration

Center for Devices and Radiological Health

Document Mail Center

10903 New Hampshire Avenue

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.** Study Risk Determination for Non-significant Risk

**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 confirm that our proposed clinical trial meets regulatory criteria for a non-significant risk medical device. The clinical trial protocol is included for review. We do not believe that the device in this clinical trial is a Significant Risk device. Specifically:

1. It is not intended as an implant and does not present a potential for serious risk to the health, safety, or welfare of a subject.
2. It is not purported or represented to be for a use in supporting or sustaining human life and does not present a potential for serious risk to the health, safety, or welfare of a subject.
3. It is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health; however, it does not present a potential for serious risk to the health, safety, or welfare of a subject; and,

*Add statements here to justify*

1. It does not otherwise present a potential for serious risk to the health, safety, or welfare of a subject.
2. The investigation is subject to prior approval by the University of Pittsburgh Institutional Review Board, which operates in compliance with the FDA regulations at 21 CFR Parts 50 and 56.

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

Respectfully,