*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 an exemption from the requirement for an IDE application

**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 confirmation that our proposed clinical trial “*insert trial title*” meets regulatory criteria for an exemption from the requirement for the submission, and FDA approval, of a sponsor-investigator IDE application.

The clinical trial protocol is included for review. We believe that the trial is exempted from the requirements for an IDE for the following reasons:

*Refer to the IDE exemption regulations at 21 CFR 812.2(c) at the link below for the appropriate criteria to list.*

[*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=812.2*](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=812.2)

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