SIGNIFICANT RISK DEVICE

July 1, 2019

*<Name of Sponsor>*

*<Address of Sponsor>*

*<Phone Number of Sponsor>*

*<Fax Number of Sponsor>*

*<Email Address of Sponsor>*

Dear Sir or Madam:

On *<Date of IRB Meeting>* the IRB reviewed the proposed protocol submitted for review under the abbreviated IDE requirements (21 CFR §812.2(b)(1)) and determined that the following protocol is a *<significant/non-significant>* risk device study:

|  |  |
| --- | --- |
| Type of Review: | *<Indicate Initial, Continuing, or Modification>* |
| Title: |  |
| Investigator: |  |
| IRB ID: |  |
| Funding: | *<Indicate “None” if there is none.>* |
| Grant Title: | *<Indicate “None” if there is none.>* |
| Grant ID: | *<Indicate “None” if there is none.>* |
| IND, IDE or HDE: | *<Indicate “None” if there is none.>* |
| Documents Reviewed: |  |

Sincerely,

IRB Manager

cc: *<Protocol Contact>*