

SIGNIFICANT RISK DEVICE

June 26, 2012

<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>