**[Investigator/Sponsor – Name, Title]**

Icahn School of Medicine at Mount Sinai

One Gustave L. Levy Place

New York, NY 10029

[date]

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Re: Application for an Investigational Device Exemption (IDE) for an investigator-initiated trial entitled: [study title**]**

To Office of Device Evaluation:

We are pleased to submit this investigator-initiated IDE application for a [brief description – including for example]:

Trial type – [retrospective, prospective – single centered, multi-centered – non-randomized, randomized – pilot study, pivotal study, continuation study]

Study Goal

Patient diagnosis

Patient Inclusion Criteria

Study Strategy

Number of patients

Number of sites/centers

1. **Certification**

 We certify that this is an original IDE application

1. **Device Information**

[manufacturer name and name of device]

1. **Sponsor Contact Information**

 Icahn School of Medicine at Mount Sinai

 One Gustave Levy Place

 New York, NY 10029 USA

 Contact: [name]

 Phone:

 Email:

1. **Manufacturers Information**

 This is not a manufacturer submission.

1. **Applicant Information**

 See above under sponsor

1. **Pre-IDE meetings**

None

1. **Waiver requests**

 None

1. **Referenced files**

The device manufacturer, [manufacturer name] has provided a ***Rights of Reference Letter***, granting the FDA permission to reference applicable device files in its review of the current application.

We thank you for your consideration of this IDE application.

Sincerely,

[PI/Sponsor Name, Title]

 Icahn School of Medicine at Mount Sinai