[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

2. Device Information

[manufacturer name and name of device]

3. Sponsor Contact Information

Icahn School of Medicine at Mount Sinai

Form version date: 7/2/13
4. Manufacturers Information

This is not a manufacturer submission.

5. Applicant Information

See above under sponsor

6. Pre-IDE meetings

None

7. Waiver requests

None

8. 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