20XX Progress Report

IDE Gxxxxx

IDE Title (if title being used)

Gxxxx/R00X

Name of Sponsor Investigator, MD

X Professor, Department

DUKE UNIVERSITY

Date of Submission

# FDA Form 3514

*The use of this form is not required, but is strongly recommended. If you choose not to use the form, ensure that the relevant information is contained in the cover letter:*

* *Statement that this is a progress report submission*
* *Device name and intended use*
* *Sponsor’s contact information*
  + *Name, address, telephone number, fax number, email address*
* *Manufacturer information* 
  + *Name, address, contact person, telephone number, fax*

*Link to the form:* [*http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf*](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf)

# Table of Contents

[1 FDA Form 3514 2](#_Toc99022073)

[2 Table of Contents 3](#_Toc99022074)

[3 General Information 4](#_Toc99022075)

[4 Study Progress 5](#_Toc99022076)

[4.1 Brief Summary of the Study Progress 5](#_Toc99022077)

[4.2 Number of Investigators/Investigational Sites 5](#_Toc99022078)

[4.3 Number of Subject Enrolled 5](#_Toc99022079)

[4.4 Number of Devices Shipped 5](#_Toc99022080)

[4.5 Brief Summary of the Results 5](#_Toc99022081)

[4.6 Summary of Anticipated and Unanticipated Adverse Effects 5](#_Toc99022082)

[4.7 Deviations from the Investigational Plan 5](#_Toc99022083)

[5 Risk Analysis 6](#_Toc99022084)

[6 Other Changes 7](#_Toc99022085)

[7 Future Plans 8](#_Toc99022086)

# General Information

*Please state your:*

1. *IDE number*
2. *Device name and indication(s) for use*
3. *Sponsor’s name address, phone numbers, and fax*
4. *Sponsor’s email address*
5. *Contact person*

# Study Progress

*(Data from the beginning of the study should be reported, unless otherwise indicated)*

## Brief Summary of the Study Progress

## Number of Investigators/Investigational Sites

*Include a list of investigators with their reviewing IRB; include both addresses.*

## Number of Subject Enrolled

## Number of Devices Shipped

## Brief Summary of the Results

## Summary of Anticipated and Unanticipated Adverse Effects

## Deviations from the Investigational Plan

*Please, describe all the deviations from the investigational plan since the last progress report.*

# Risk Analysis

*A thorough risk analysis and risk mitigation strategies are critical for the FDA’s decision to allow a study to continue. Update the risk analysis from your initial application with any relevant changes. Include a summary of any new adverse information (since the last progress report) that may affect the risk analysis. This includes preclinical data, animal studies, foreign data, clinical studies, etc. For more details on what to include in the risk analysis, please see the original IDE template.*

*Also, please attach the reprints of any articles published from data collection from this study.*

*Present a new risk analysis, if necessary, based on any new information and study progress.*

# Other Changes

*Summary of any changes in the manufacturing process and quality control, including changes that have not been submitted as a supplemental application.*

*Summary of all changes in the investigational plan that were not required to be submitted in a supplemental application.*

# Future Plans

*Progress towards product approval, including a projected date for PMA or 510(k) submission.*

*If there are any plans to change the investigation, e.g., to expand the study size or indications, to discontinue portions of the investigation or to change manufacturing practices, please state in this section*. *(NOTE: Actual proposals for these changes should be made in a separate supplemental application since they may require prior approval).*