**20[XX] IDE ANNUAL PROGRESS REPORT**

**IDE # [XXXXX]**

**[DEVICE NAME]**

**[SPONSOR NAME]**

**[ADDRESS]**

**[PHONE #]**

**[FAX NUMBER]**

**[EMAIL]**

**[CONTACT PERSON]**

**REPORTING PERIOD: [XX MONTH 20XX] – [XX MONTH 20XX]**

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# BASIC ELEMENTS

*Cover sheet Form FDA 3514 is provided on this* [*FDA webpage*](http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/MedicalDeviceForms/) *and covers most of the information in this section. If not used, provide the following information.*

## 1.1 Device Name and Indication(s) for Use

## 1.2 IDE Number

## 1.3 Sponsor Information

*Include Sponsor’s name, address, phone number, fax number, and email address.*

## 1.4 Contact person

# STUDY PROGRESS

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

## 2.1 Investigational Plan Progress

*Brief summary of the study progress in relation to the investigational plan*

## 2.2 Investigators and Investigational Sites

*Attach a list of investigators, and list the number of investigators and investigational sites*

## 2.3 Subjects

*State the number of subjects enrolled. This can be done by model or otherwise*

## 2.4 Devices Shipped

*State the number of devices shipped*

## 2.5 Results

*Briefly summarize the results of the study so far*

## 2.6 Adverse Effects

*Summarize any anticipated or unanticipated adverse effects*

## 2.7 Deviations

*Describe any deviations from the investigational plan. These should only be deviations since the last progress report*

# RISK ANALYSIS

## 3.1 Adverse Information

*Summarize any new adverse information that may affect risk analysis. This includes pre-clinical, animal studies, foreign, clinical data etc.*

## 3.2 Published Data

*Reprints of any articles published from data collected from the study*

## 3.3 New Risk Analysis

*Summarize any new risk analysis*

# 4. OTHER CHANGES

## 4.1 Manufacturing and Quality Control

*Summary of changes in manufacturing practices and quality control*

## 4.2 Investigational Plan

*Summary of changes in investigational plan not required to be submitted in an IDE supplement*

# 5. FUTURE PLANS

## 5.1 Approval Progress

*Progress towards approval or clearance. Include projected date of PMA or 510(k) submission.*

## 5.2 Plans for Change

*Any plans to change the investigation in the future.*