***Please use UA letterhead issued by your own department.***

Investigational Device Exemption Progress Report

*IDE Gxxxxx*

*IDE Title (if title being used)*

Period Covered

*From MM-DD-YYYY to MM-DD-YYYY*

*Name of Sponsor Investigator, MD*

*Title*

*Department*

University of Arizona

*Date of Submission*

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# 1. GENERAL INFORMATION

*If you chose to use Cover Sheet-Form FDA 3514, most of the information that should be presented in this section is already captured in the form.*

*If you chose not to use the form, please state your:*

*1) IDE number*

*2) Device name and indication(s) for use*

*3) Sponsor’s name address, phone numbers and fax*

*4) Contact person*

# 2. STUDY PROGRESS

*(Data from the beginning of the study should not be reported, unless otherwise indicated)*

## 2.1 Brief Summary of the Study Progress

1. *Number of Investigators/Investigational Sites (Include a list of investigators.)*
2. *Number of Subject Enrolled*
3. *Number of Devices Shipped*
4. *Brief Summary of the Results*
5. *Summary of Anticipated and Unanticipated Adverse Effects*
6. *Deviations from the Investigational Plan (Describe all the deviations from the investigational plan since the last progress report.)*

## 2.2 Number of investigators/Investigational Sites

## 2.3 Number of Subject Enrolled

## 2.4 Number of Device Shipped

## 2.5 Brief Summary of the Results

## 2.6 Summary of Anticipated and Unanticipated Adverse Effects

## 2.7 Deviations from the Investigational Plan

*Describe all the deviations from the investigational plan since the last progress report.*

# 3. RISK ANALYSIS

*Summary of any new adverse information (since the last progress report) that may affect the risk analysis. This include preclinical data, animal studies, foreign data, clinical studies, etc.*

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

*Present the new risk analysis if necessary, based on the new information that have been collected and on study progress*

# 4. OTHER CHANGES

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

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

# 5. FUTURE PLANS

*Progress towards product approval with projected data from the 510(k) or PMA*

*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*

*where some of them would require prior approval).*