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

**IDE Progress Report**

*Investigator-Sponsor’s Name*

*Academic Department of Investigator-Sponsor*

University of Arizona

*Address*

Date: *MM DD, YYYY*

Food and Drug Administration

Center for Devices and Radiological Health

*Please refer to your letter from the FDA acknowledging the receipt of your IDE application to identify the specific FDA contact person, and mailing address, to whom the Progress Report should be sent.*

**Re: IDE Progress Report – IDE #** *IDE Number*

Dear: *Name of FDA Contact Person*

Enclosed please find three copies (the original and 2 photocopies) of the required annual Progress Report for IDE Number *IDE Number*.

Thank you for incorporating this Progress Report into the respective IDE file.

Sincerely,

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Signature of Investigator-Sponsor Printed Name of Investigator-Sponsor

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Phone # of Investigator-Sponsor FAX # of Investigator-Sponsor

**IDE Progress Report**

**IDE Number:** *Specify IDE number*

**Device Name:** *Specify device name*

**Indication(s) for Device Use:** *Specify the proposed indication(s) for use of the device*

**Period Covered in this Submission** *From MM/DD/YYYY to MM/DD/YYYY*

**Date of Original IDE Submission:** *Specify date of initial submission*

**A. Study Progress**

*Note: Data accruing from the initiation of the clinical study (studies) of the device should be reported, unless otherwise indicated.*

* 1. **Summary of Study Progress in Relation to Investigational Plan:**

*Provide a brief summary of the study progress in relation to the current investigational plan.*

* 1. **Investigators/Investigational sites:**

*Provide a current listing, by clinical protocol title(s) or proposed clinical indication(s), of all principal investigators and corresponding investigational sites involved in the clinical evaluation of the device.*

* 1. **Number of Subjects Enrolled:**

*Provide, by clinical protocol title(s) or proposed clinical indication(s), the number of subjects currently enrolled at all study sites. Include in your response patient accountability information, with the following information for each follow-up interval: number due for follow-up; number not yet due for follow-up; number followed; number that missed follow-up; number lost to follow-up or withdrawn; and number deceased. In addition, please specify the number eligible, and the number with data for each key parameter at each follow-up interval.*

* 1. **Number of Devices Shipped:**

*Provide a listing, by clinical site, of the number of devices that have been shipped to date. If not applicable, specify “Not applicable – use of device limited to investigator-sponsor/investigator-sponsor study site.”*

* 1. **Summary of Study Results:**

*Provide, by clinical protocol title(s) or proposed clinical indication(s), a brief summary of corresponding study results. (Note that this information can be addressed through the use of tables or graphs containing compiled patient-subject data.)*

* 1. **Summary of Anticipated and Unanticipated Adverse Device Effects:**

*Provide, by clinical protocol or clinical indication(s), a summary of all anticipated and unanticipated adverse device effects observed or reported to date. If there have been no observed or reported anticipated or unanticipated adverse device effects, specifically state this.*

*(Note: an “adverse device effect” is defined by FDA regulation as “any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, the device; or any other serious problem associated with the device that relates to the rights, safety, or welfare of subjects.”)*

*A “serious adverse effect” means “any adverse effect that results in any of the following outcomes: death, a life-threatening adverse effect, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect.”*

*“Associated with the device” means “there is a reasonable probability that the adverse effect may have been caused by the device.”*

*“Anticipated/unanticipated” means that “the adverse effect, problem, or death was/was not previously identified in nature, severity, or degree of incidence in the investigational plan or IDE application (including a supplementary plan or application”).*

* 1. **Deviations from the Investigational Plan by Investigators:**

*Provide a description, by listed principal investigator, of any deviations from the investigational plan that have occurred since the last progress report.*

**B. Risk Analysis**

1. **Summary of New Adverse Information**

*Provide a brief summary of any new adverse information (i.e., non-clinical laboratory or animal data, foreign data, clinical study results) related to the device (or to similar devices) that has come to the attention of the investigator-sponsor since the last progress report and that may affect the current risk analysis of the device. If no such information has been identified, specifically state this.*

1. **Reprints of Published Articles:**

*Provide a listing of all published articles that address data collected from studies of the device. For each listed publication, incorporate into a referenced Appendix, a reprint or copy of the publication. If there are no such published articles, specifically state this.*

1. **New Risk Analysis**

*Provide a new risk analysis, if necessary, based on new information regarding the device and/or based on the progress of clinical study (studies) of the device. If a new risk analysis is not deemed to be necessary, specifically state this.*

**C. Other Changes**

1. **Changes in Manufacturing Practices and Quality Control**

*Provide a summary of any changes in manufacturing practices and/or quality control procedures; including changes not previously reported in a Supplemental Application. If none, specifically state this.*

1. **Changes in Investigational Plan**

*Provide a summary of all changes in the investigational plan that were not required to be previously submitted in a Supplemental Application. If none, specifically state this.*

1. **Future Plans**
2. **Progress Toward Product Approval**

*Provide a summary of progress toward product approval; to include the projected date of PMA or 510(K) submission. If the device will be licensed to an external company for further development after the completion of feasibility studies, specifically state this.*

1. **Plans to Change the Investigational Plan**

*Address any plans to change the investigational plan; e.g. to expand the study size or indications, to discontinue portions of the investigation, or to change manufacturing practices. (Note that actual proposals for such changes must continue to be submitted prospectively to the FDA in the form of separate Supplemental Applications.) If there are currently no such plans, specifically state this.*