**IDE Annual Report (20XX- 20XX)**

**Reporting Date**

**Summary of study status**

 **IDE**

**Title**:

 **IRB#**

 **CT.gov #**

**PURPOSE**:

.

 **Statement if study is completed**: N/A

**Enrollment/Demographics:**

|  |  |
| --- | --- |
| Subject Totals |  |
| Number of Subjects Planned |  |
| Number of Subjects Enrolled |  |
| Number of Subjects Completed |  |
| Number of Subjects Withdrawn/Dropped |  |

|  |  |
| --- | --- |
| Race and Gender |  |
| American Indian/Alaskan Native |  |
| Asian |  |
| Black or African American |  |
| Native Hawaiian or Other pacific Islander |  |
| Caucasian | 0 |
| Hispanic or Latino | 0 |

|  |  |
| --- | --- |
| Age Range |  |
|  |  |

**IDE Summary Information for the previous year (clinical & non-clinical) Insert table showing any serious adverse events that have occurred in the past year.**

**A summary of all IDE safety reports submitted during the past year.**

**A list of subjects who died during participation in the investigation, with the cause of death for each subject**.

**A list of subjects who dropped out during the course of the investigation in association with any adverse experience, whether or not thought to be device-related.**

**A brief description of what, if anything, was obtained that is pertinent to an understanding of the device’s action.**

**A list of the preclinical studies (including animal studies) completed or in progress during the past year and a summary of the major preclinical findings**.

**A summary of any significant manufacturing or microbiological changes made during the past year**.

**A description of the general investigational plan for the coming**

**year to replace that submitted 1 year earlier**.

**A description of any protocol modifications made during the previous year and not previously reported to the IDE in a protocol amendment**.