

## Suggested Format for IDE Progress Report

### I. The Basics

- IDE Number
- Device name and indication for use
- Sponsor's name, address and phone number
- Contact person

### II. Study Progress

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

- Brief summary of study progress in relation to investigational plan
- Number of investigators/investigational sites (attach list of investigators)
- Number of subjects enrolled (by indication or model)
- Number of devices shipped
- Brief summary of results
- Summary of anticipated and unanticipated adverse effects
- Number of emergency and/or compassionate use cases, summary of outcome/safety information and any adverse effects
- Description of any deviations from the investigational plan by investigators (since last progress report)

### III. Risk Analysis

- Summary of any new adverse information (since last progress report) that may affect the risk analysis; this includes preclinical data, animal studies, foreign data, clinical studies, experience with emergency use and/or compassionate use, etc.
- Reprints of any articles published from data collected from this study
- New risk analysis, if necessary, based on new information and on study progress

### IV. Other Changes

- Summary of any changes in manufacturing practices and quality control (including changes not reported in a supplemental application)
- Summary of all changes in investigational plan not required to be submitted in a supplemental application

### V. Future Plans

- Progress toward product approval, with projected date of PMA or 510(k) submission
- Any plans to change investigation, e.g., to expand study size or indications, to discontinue portions of the investigation or to change manufacturing practices (**NOTE:** Actual proposals for change should be made in a separate supplemental application)

March 2004