STANDARD OPERATING PROCEDURE

Title: Medical Device Reporting: USA

Effective Date: _____

Approvals (Signature and Date):

_____	_____	_____
Responsible Department Head	Technical Authority	QA/QC Manager

1. PURPOSE

1.1 To describe the procedure for collecting information regarding reportable events and filing the required reports. This procedure is specific for reporting to the U.S. Food and Drug Administration. A separate procedure, SOP 09-0178, describes reporting of events to European Competent Authorities.

2. SCOPE

2.1 The MDR (Medical Device Reporting) regulation is only applicable to marketed devices.

2.2 Products that are distributed under IDE are not subject to MDR in the United States. However, if they are marketed in Europe, incidents must be reported to [illegible] responsible Regulatory Manager in Europe and reported in the U.S. Incidents that occur and are related to a product under IDE regulations are subject to the record keeping and reporting requirements outlined in 21 CFR Part 812.150. Consult the appropriate Clinical SOP for information on reporting during a clinical trial.

3. RESPONSIBILITY

3.1 Reporting of Complaints

3.1.1 Every employee of [illegible] (in the United States and in Europe) is responsible for reporting all complaints to Customer Service in the United States. (See SOP 09-0011) If employees become aware of information that reasonably suggests that one of the devices marketed by [illegible] may have caused or contributed to a death or serious injury or a device has malfunctioned and would be likely to cause a death or serious injury they should report the event **immediately**.

3.2 Recording of Complaints

3.2.1 Customer Service is responsible for recording all complaints on CAR forms. If any event is reported by a health professional as an MDR reportable event, or if the individual recording the complaint believes that the event may meet the definition of an MDR reportable event, Customer Service will alert the responsible individual and send them a copy of the complaint within 24 hours. The responsible people are designated below:

3.2.1.1 United States: Medical Director, USA.

3.2.1.2 Europe: Medical Director, Europe.

3.2.2 The Clinical Affairs Department is responsible for determining whether or not an event meets the definition of an MDR reportable event. The Clinical Affairs Department is responsible for making a decision on whether or not an event is reportable within 24 hours.

3.3 Reviewing the MDR and Filing the MDR with the FDA and European Authorities