ATTACHMENT E

SUMMARY OF CORRECTIONS AND REMOVALS - 21 CFR 806 REQUIREMENTS

1. Reports of Corrections and Removals – 21 CFR 806.10

Each device manufacturer and importer shall submit a written report to FDA of any correction or removal of a device IF the correction or removal was initiated to:

a) Reduce a risk to health posed by the device; or

b) Remedy a violation of the act caused by the device which may present a risk to health.

c) Reports in items (a) and (b) above are NOT required IF:

i. The information has already been reported to FDA under the MDR regulation, 21 CFR 803 or under 21 CFR 1004.

NOTE: The MDR report must:
- Be submitted within the 10 day reporting timeframe specified in 21 CFR 806.10, and
- Contain all the information required in a Report of Correction and Removal as specified in 21 CFR 806.10(c)(1-13).

ii. The correction or removal meets the following criteria:

- When the action is taken to improve the performance or quality of a device but does not reduce a risk to health posed by the device or remedy a violation of the act caused by the device

- Market withdrawals, 21 CFR 806.2(h) and 21 CFR 7.3(j) - a correction or removal of a distributed device that involves a minor violation of the act that would not be subject to legal action by FDA or that involves no violation of the act, e.g., normal stock rotation practices

- Routine servicing, 21 CFR 806.2(k) - any regularly scheduled maintenance of a device, including the replacement of parts at the end of their normal life expectancy, e.g., calibration, replacement batteries, and responses to normal wear and tear. However, repairs of an unexpected nature, replacement of parts earlier than their normal life expectancy, or identical repairs or replacement of multiple units of a device, are not routine servicing. Such service should be “trended” to determine if a problem exists

- Stock recoveries, 21 CFR 806.2(l) and 21 CFR 7.3(k) - the correction or removal of a device that has not been marketed or that has not left the direct control of the manufacturer, i.e., the device is located on the premises owned, or under the control of,the manufacturer, and no portion of the lot, model, code, or other relevant unit involved in the corrective or removal action has been released for sale or use.

d) The key concept for determining when an event is reportable is the definition of risk to health found in 21 CFR 806.2(j):

i. A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; (Class I Recalls) or

ii. That use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote, (Class II Recall).

NOTE: Assistance regarding risk to health determinations can be obtained from your district's recall coordinator or CDRH's recall staff in the Office of Compliance.

e) Manufacturers and Importers are required to submit a Corrections and Removals report to the appropriate FDA District Office within 10 working days of the decision to initiate a correction. A list of the information required in the report is listed in 21 CFR 806.10(c)(1-13).

f) A foreign manufacturer or owner or operator of devices must also submit reports of corrections and removals.

NOTE: The regulation does not specify where foreign device manufacturers should send their Corrections and Removals reports. FDA, however, expects foreign Corrections and Removals reports to be submitted to the District Office where the product is being imported.

2. <u>Records of Corrections and Removals required to be maintained, but not required to be reported, to FDA - 21 CFR 806.20:</u>

a) Each device manufacturer and importer who initiates a correction or removal of a device that is NOT required to be reported to FDA under Section 806.10 shall keep a record of each correction or removal.

b) Records of corrections and removals NOT reported to FDA must contain the following information:

i. The brand name, common or usual name, classification name, product code (if known), and the intended use of the device.

ii. The model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

iii. A description of the event(s) giving rise to the information reported and the corrective or removal action that has been, and is expected to be taken.

iv. Justification for NOT reporting the correction or removal action to FDA, which shall contain conclusions and any follow-ups, and be reviewed and evaluated by a designated person.

v. A copy of all communications regarding the correction or removal.

c) Manufacturers shall retain all records required under this section for a period of 2 years beyond the expected life of the device, even if the respective firm has ceased to manufacturer or import the devices.

In addition, Corrections and Removal files/records must be transferred to any new/subsequent manufacturer or importer of the device and maintained for the required period of time.

REPORTS OF CORRECTIONS AND REMOVALS REFERENCE MATERIAL

1. Title 21 CFR Part 806, Medical Devices; Reports of Corrections and Removals.

2. Title 21 CFR Part 7, Enforcement Policy, (Recalls (Including Product Corrections)-Guidelines on Policy, Procedures, and Industry Responsibilities.

3. Title 21 CFR Part 803, Medical Device User Facility and Manufacturer Reporting.