APPENDIX D

MedSun Report Form for Mailed & Faxed Reports

FDA Form 3670
OMB 0910-0471
Exp. Date 12/31/2010

Section 1: Contact Information

User Facility Name: _____

Address: _____

_____

Contact's Name: _____

Contact's Phone #: _____

Contact's Fax #: _____

Contact's email address: _____

Contact's Occupation: _____

Name of initial reporter: _____

Address of initial reporter: _____

_____

Section 2: Event Information

Event Title: (to help you identify this event)

When did the event happen? (mm/dd/yyyy)

How many days ago did you first become aware of the event?

- Less than or equal to 10 days
- More than 10 days ago

Date of this report: (mm/dd/yyyy) _____

Section 2: Event Information (continued)

Where did this event occur:

- Ambulatory surgical facility
- Home
- Hospital
- NICU
- Nursing home
- Outpatient diagnostic facility
- Outpatient treatment facility
- PICU
- Not known
- Not applicable
- Physician's office
- Other: (specify) _____

If you checked "Hospital," where in the hospital did this event occur?

- Critical Care
- ER
- Patient room
- OR
- Skilled nursing unit
- Other: (specify) _____
- Not known
- Not applicable

The device(s) may have caused or contributed to: (check all that apply)

- Death
  date: (mm/dd/yyyy) _____
- Serious injury
- Minor injury to the patient or health care provider *(indicates voluntary report)*
- Potential for patient harm *(indicates voluntary report)*
- Potential harm to a health care provider *(indicates voluntary report)*
- Not known
- Not applicable

If you checked "Serious injury," please answer the following questions:

Was intervention required to prevent permanent impairment or damage?

- Yes
- No
- Not known
- Not applicable

Outcomes attributed to serious injury: (check all that apply)

- Congenital anomaly
- Disability
- Hospitalization, initial or prolonged
- Other: (please describe the outcome) _____
- Life threatening
- Not known
- Not applicable

Section 2: Event Information (continued)

Was there a problem with the device? (such as a defect, malfunction, break, etc.)

- Yes
- No
- Not known
- Not applicable

If you checked "Yes," what problem did the user have? (check all that apply)

- Device failed (broke, couldn't get it to work, stopped working, etc.)
- Device malfunction (the device did not do what it was supposed to do)
- Device was hard to use
- Not known
- Not applicable
- Other: (specify) _____

Was someone directly "operating" the device at the time of the event?

- Yes
- No
- Not known
- Not applicable

If you checked "Yes," who was operating the device? (check all that apply)

- Allied Health Provider
- Doctor
- Family member/visitor
- Nurse
- Patient
- Not known
- Not applicable
- Other: (specify-NO NAMES) _____

Were there other devices being used on the patient at the time of the event that may have caused or contributed to the event?

_____

_____

_____

Were there other therapies being used on the patient at the time of the event that may have caused or contributed to the event? (check all that apply)

- Cardiac drugs
- Immunotherapy
- Long-term antibiotics
- Prenatal medication
- No other therapies
- Chemotherapy—date: (mm/dd/yyyy) _____
- Dialysis—date: (mm/dd/yyyy) _____
- Hormonal Replacement Therapy
- Not known
- Not applicable
- Other: (list other therapies) _____

Section 2: Event Information (continued)

Describe the event or problem. Please provide as much detail as possible.

Section 2: Event Information (continued)

What was the original intended procedure?

What was the health professional's impression of how the device may have caused or contributed to the adverse event?

Can the health professional's impression be included in the event?

- Yes
- No

Section 3: Patient Information

PLEASE USE A SEPARATE PAGE FOR EACH PERSON INVOLVED

Patient Identifier: (use something that will help you remember who the patient is. DO NOT USE the patient's name, initials, SSN, date of birth, medical record number of other identifiers) 8 Character Limit.

_____

Patient's age: _____

- Years
- Months
- Weeks
- Days
- Do not know
- Not applicable

Patient's sex:

- Male
- Female
- Not known
- Not applicable

Patient's weight: _____

- Pounds
- Ounces
- Do not know
- Kilograms
- Grams
- Not applicable

Patient's ethnic background: *[Optional]*

- American Indian or Alaskan Native
- Asian
- Black or African American
- Hispanic or Latino
- Native Hawaiian or other Pacific Islander
- White
- Unknown
- Not applicable

Section 3: Patient Information (continued)

Did the patient have any of the following preexisting characteristics that may have contributed to the event? (check all that apply)

- Allergies (describe below)
- Alcohol/drug use
- COPD
- Coronary heart disease
- Diabetes
- Hepatic/renal dysfunction
- Hypertension
- Immuno-compromised
- Morbidly obese
- Pneumonia
- Other: (describe below)
- Pregnancy
- Premature infant
- Smoking
- Status post total hysterectomy or salpingioherectomy
- Relevant accidents (i.e. hit head) (describe below)
- Stroke
- Surgery
- No preexisting characteristics
- Not known
- Not applicable

Please use this space to describe the relevant accident preceding the event, the relevant patient allergies, (i.e. latex allergy, a particular medication allergy, an allergy to a particular material or biomaterial, etc.) and/or other preexisting characteristics.

Please describe the relevant accident preceding the event

Other characteristics or medical conditions.

Section 3: Patient Information (continued)

Please provide any other information about the patient that may have influenced the outcome of the event:

Section 4: Device Information

PLEASE USE A SEPARATE PAGE FOR EACH DEVICE INVOLVED

Device manufacturer's name: _____

Street address: _____

City: _____ **State:** _____ **Zip Code:** _____

When do you plan to return the device to the manufacturer?
date: (mm/dd/yyyy) [Optional]

Device brand name: _____

Type of device: _____

Approximate age of device: _____

If the device is a disposable device, was the packaging saved?

- Yes
- No
- Not known
- Not applicable

Is this a single use device that was reprocessed and reused on a patient?

- Yes
- No
- Unknown

If "Yes," please fill in all that are available:

Name of Reprocessor: _____

Reprocessor's Street Address: _____

City: _____

State: _____

Zip: _____

Is this a laboratory device or laboratory test?

- Yes
- No

If "Yes," please answer the following questions:

Did the problem involve: (check all that apply)

- The reagent
- The instrument

- Single use or rapid test
- Other: (specify)

Section 4: Device Information (continued)

Is this a recurrent problem with this assay, test kit, or instrument?

- Yes
- No

If "Yes," please provide additional details:

Which of the following problems did you observe? (check all that apply)

- Calibration
- Reproducibility
- Analytical specificity
- Questionable patient results
- Inadequate or unclear instructions for use
- Performance described in package insert not met
- Patient related problems
- Repeated error message
- Analytical sensitivity
- Quality control
- Reagent(s)
- Poor test / instrument design
- Specimen problems
- Other: (specify)

Please describe any follow-up actions below: (check all that apply)

- Repeated assay, results OK reported out
- Repeated assay, still problems
- Replaced reagents
- Opened new lot
- Manufacturer notified
- Called for service, received adequate response from manufacturer
- Product not available to return to manufacturer
- Discontinued all use of product
- Not known
- Not applicable
- Other: (specify)

Device numbers: (please fill in all that are available)

Device serial #: _____

Device model #: _____

Device lot #: _____

Device catalog #: _____

Other device #: _____

Expiration date: (mm/dd/yyyy) _____

Has the facility discontinued use of the device due to the event? *[Optional]*

- Yes
- Not known

- No
- Not applicable

Section 4: Device Information (continued)

If the device was implanted, give the implant date: (mm/dd/yyyy) _____

If the device was explanted, give the explant date: (mm/dd/yyyy) _____

Was the device returned to the manufacturer?

- Yes
- No
- Not known
- Not applicable

If you checked "Yes," when was returned? (mm/dd/yyyy) _____

How was the device returned to the manufacturer?

- Returned to the manufacturer by mail
- Given to manufacturer field representative
- Other method (please specify):

If you checked "No," where is the device now?

- Retained by the patient or patient representative
- Discarded
- Retained by the hospital
- Other (please specify):

Is the device available at your facility for evaluation?

- Yes
- No
- Not known
- Not applicable

Have you made the manufacturer aware of this problem/issue?

- Yes
- No
- No known

If you checked "Yes," what has been the manufacturer's response?

Section 4: Device Information (continued)

Can this information be made available to the public?

- Yes
- No

Do you intend to return the device to the manufacturer in the near future?

- Yes
- No

When do you plan to return the device to the manufacturer?
date: (mm/dd/yyyy)

Section 5: Test Information

Please enter all relevant tests/laboratory data: (enter each test separately)

Test Type/ Test Performed	Date (mm/dd/yyyy)	Results