



INVESTIGATIONAL DEVICE DATA SHEET
RUSH-PRESBYTERIAN-ST. LUKE'S MEDICAL CENTER

For information on medical devices, consult the FDA Information Sheets on the internet at <http://www.fda.gov>; hard copies are available on the Office of Research Affairs.

PRINCIPAL INVESTIGATOR: _____

PROTOCOL TITLE AND NO.: _____

DEVICE NAME: (Give company name and a descriptive name): _____

ID or IDE Number (For significant risk devices): (A copy of the FDA authorization letter **MUST** be attached): _____

INDICATIONS FOR USE: _____

SIDE EFFECTS:

PRIOR USAGE BY OTHERS: _____
WHERE? _____

WHEN? _____

STUDY SITE: Inpatient Outpatient Other: _____

PHYSICIAN'S (Other than PI) WHO WILL BE UTILIZING DEVICE:

INDIVIDUAL TO CONTACT (24hours/day) REGARDING PROBLEMS WITH DEVICE:

Name

Telephone