

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139	DATE(S) OF INSPECTION 11/30/2015-12/3/2015
	FBI NUMBER 3011760218

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Cindy M. Basinski, M.D., P.I.

FIRM NAME Basinski, Cindy, MD	STREET ADDRESS 3922 Venetian Way Ste 1
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CITY, STATE, ZIP CODE, COUNTRY Newburgh, IN 47630-7958	TYPE ESTABLISHMENT INSPECTED Clinical Investigator
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This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

An investigation was not conducted in accordance with the signed agreement and the investigational plan .

Specifically,

Per protocol 16973 version 1 dated 7/24/13 section 7.5.1.4 Reporting of serious adverse events and near incidents states "All SAEs and near incidents (ADEs) occurring during the observation period ... must immediately (within 24 hours of the Investigator's awareness) be reported"

- Subject (b) (6) had an SAE (b) (4)) suspected to have occurred during procedure on 5/13/14, this was not reported to the sponsor until 5/20/14 which is more than 24 hours. Furthermore on 8/18/14, it was noted during an (b) (4) that the left device had migrated (b) (4) but the AE was not updated to reflect this until 8/21/14. On 9/26/14, the subject had a (b) (4) procedure and it was determined that (b) (4) . The IRB was not notified of this event until 1/6/15.
- Subject (b) (6) had (b) (4) known to have occurred on 7/3/14 (b) (4)) due to a (b) (4) , this was thought to be related to injury that occurred during the previous (b) (4) placement. This was not reported to the sponsor until 12/4/14 which is more than 24 hours and the IRB was not notified of this event until 1/6/15.

Per protocol 16973 version 1 dated 7/24/13 section 7.5.1.1 states adverse events are any untoward medical occurrence in a clinical investigation subject from the time of signing of the informed consent.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Corrine M Carter, Investigator	DATE ISSUED 12/3/2015
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Adverse event forms were not completed for the following subjects:

- Subject (b) (6) reported "still having pain" on 3/13/14 and requested more pain medication two days after her procedure
- Subject (b) (6) reported that she had "new onset urinary frequency and urgency" on 5/6/14, had a urinalysis with "trace blood" on 5/8/14, was "unhappy with current bleeding pattern" on 8/28/14, had daily bleeding for two months at an unscheduled visit on 2/9/14, and "pain" on 9/28/15

OBSERVATION 2

Records of each subject's case history are not all accurate and current .

Specifically,

7 out of 33 subjects reviewed had incomplete Demographics/Medical History screening information at the time of screening for the question "Is there anything remarkable in the subject's health history that has not been recorded?"

- Subject 1400010027 had "menorrhagia" added to their medical history on 9/2/15, however screening occurred 4/3/14
- Subject 140010028 had "menorrhagia which has been controlled with (b) (4)" added to their medical history on 9/22/15, however screening occurred 4/10/14
- Subject (b) (6) had "menorrhagia" added to their medical history on 4/8/15, however screening occurred 1/16/14
- Subject 140010022 had "ITP" (immune thrombocytopenic purpura) added to their medical history on 9/2/15, however screening occurred 3/3/14
- Subject 140010017 had ""depression" added to their medical history on 9/2/15, however screening occurred 2/6/14
- Subject 140010014 had "depression" and "yeast infections" added to their medical history on

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- 9/2/15, however screening occurred 1/23/14
- Subject 140010006 had "depression" added to their medical history on 9/2/15, however screening occurred 12/5/13

Annotations to Observations

Observation 1: Not annotated
Observation 2: Not annotated

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