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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 8050 Marshall Drive, Suite 205<br>Lenexa, KS 66214<br>(913)495-5100 Fax:(913)495-5115 | 2/9/2026-2/13/2026 |
| | FEI NUMBER<br>3042247790 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kevin E. Miller, MD, Principal Investigator

| FIRM NAME | STREET ADDRESS |
|---|---|
| Kevin E. Miller, MD | Cypress Medical Research Center, Llc,<br>9300 E 29th St N Suite 104 |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Wichita, KS 67226-3007 | Clinical Investigator |

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:**

***The following observations pertain the review of CIP: IU024- A Prospective, Randomized Clinical Trial Evaluating INTIBIA™ an Investigational Implantable Tibial Nerve Stimulator, Through 24-Months (INTIBIA Pivotal Study)***

**OBSERVATION 1**

Subjects were allowed to participate in an investigation prior to obtaining IRB approval to conduct the investigation.

Specifically, study activities (consenting and screening) were conducted at the clinical practice on (b) (4) before IRB approval of the research location. The IRB approved this site on 21 July 2022. Subject (b) (6), (b) completed their baseline visit at this location on (b) (4), (b) (6), (b) (7)(C) before approval.

**OBSERVATION 2**

An investigation was not conducted according to the investigational plan.

Specifically,

1. Subject (b) (6), (b) (7)(C) received the INTIBIA device implant on (b) (6), (b) (7)(C) A positive urinalysis from (b) (6), (b) (7)(C) was sent for culture, and results received on (b) (6), (b) (7)(C) Per Protocol Section (b) (4) urinary tract infections must be treated and a negative urinalysis confirmed before implantation. The required confirmatory urine test was not performed prior to implant of the device.

2. Subject (b) (6), (b) (7)(C) completed baseline assessments on (b) (6), (b) (7)(C) but postponed the implant procedure. The subject was not screen failed.

**SEE REVERSE OF THIS PAGE**

EMPLOYEE(S) SIGNATURE
Theressa B Smith, Investigator

X Theressa B Smith
Investigator
Signed By: Theressa B. Smith -S
Date Signed: 02-13-2026
16:15:43

DATE ISSUED
2/13/2026

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Upon return on (b) (6), (b) (7)(C) days later), critical baseline assessments were not repeated, including:

- Post-void residual (PVR) testing (Exclusion #3)
- Physical exam
- Quality of life questionnaires (e.g. ICIQ-UI, OAB-qSF, EA-5D-5L)

The questionnaires are time-sensitive: ICIQ-UI and OAB-qSF require (b) (4) recall, while EA-5D-5L requires same-day health status; therefore, the original assessments are unrepresentative of the subject's current status at the rescheduled visit.

**OBSERVATION 3**

Records for each subject concerning previous medical history and condition during the course of the investigation are not all accurate and complete.

Specifically,

1. No adverse event has been reported for the (b) (6), (b) (7)(C) injury experienced by Subject (b) (6), (b) (7)(C) noted to have occurred during a surgical procedure in (b) (6), (b) (7)(C) There is no evidence attempts to obtain hospitalization records were undertaken.

2. All historical medications taken for (b) (6), (b) (7)(C) have not been recorded for the following subjects: Subject (b) (6), (b) (7)(C) Subject (b) (6), (b) (7)(C) and (b) (6), (b) (7)(C)

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Theressa B Smith, Investigator

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."