DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave., Bldg 66-3513 Silver Spring, MD 20993-0002 301-796-5490 Fax: 301-847-8136 www.fda.gov	12/05/2022-12/15/2022
	FEI NUMBER 3010350335

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Krishnamoorthy Murugesh, CEO

FIRM NAME	STREET ADDRESS
DyAnsys India Pvt. Ltd.	Meerlan Towers, 1st Floor, No. 33 Hanumantha Rd, Balaji Nagar, Royapettah
CITY, STATE, ZIP CODE, COUNTRY Chennai 600 014 India	TYPE ESTABLISHMENT INSPECTED Medical Device Sponsor

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 to study protocol DPN/First Relief/01Version/2018 (b)(4)

(b)(4) (b)(4) (b)(4)

OBSERVATION 1

As the sponsor of this single- site clinical trial, conducted wholly outside the United States in support of a pre-market notification submission, I found you failed to assure the study was conducted in accordance with Good Clinical Practice.

Specifically,

A. You could not provide documentation confirming that the clinical investigator had obtained informed consent from any of the - subjects screened for the study. - of those subjects were enrolled and received at least one device application.

B. You did not assure that the investigational plan was followed. Including but not limited to:

- The inclusion criteria listed in the protocol (b)(4) requires subjects to have an average pain score of (b)(4) prior to randomization as assessed by the Brief Pain Inventory (BPI) and Visual Analog Scale for Pain (VAS). The inclusion criteria listed in the case report forms required an average pain score of - for study enrollment.

- The protocol (b)(4) says that subjects will be asked to keep a patient diary noting the day and date they place the study device and any adverse events experienced. Subject diaries were not used for the study.

SEE REVERSE OF THIS PAGE	Courtney N. Long, Investigator	Courtney N. Long -S Digitally signed by Courtney N. Long -S Date: 2022.12.15 12:54:50 -05'30'	DATE ISSUED 12/15/2022

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- The protocol (b)(4) says that blood will be obtained for fasting blood glucose (FBG), postprandial blood glucose (PLBS), glycated hemoglobin (HbA1C) and thyroid profile. Thyroid profiles were not performed for any of the - subject files reviewed.

- The protocol (b)(4) says that the following objective and subjective tests will be performed at all study visits:
  Brief Pain Inventory (BPI)
  Pain Intensity Visual Analog Scale (VAS)
  Neuropathic Pain Score Inventory (NPSI)
  Neuropathic Disability Score (NDS)
  Semmes-Weinstein 10g Monofilament Test
  Vibration Perception Threshold via biothesiometer (VPT)
  Pinprick Sensory Threshold (PPT)
  Patellar Reflex Response Test (Standard Patellar Hammer)

- The following tests were not performed at any of the - study visits after Enrollment (Baseline):
  Brief Pain Inventory (BPI)
  Neuropathic Pain Score Inventory (NPSI)
  Neuropathic Disability Score (NDS)
  Semmes-Weinstein 10g Monofilament Test
  Pinprick Sensory Threshold (PPT)
  Patellar Reflex Response Test (Standard Patellar Hammer)

- The Overall Neuropathy Limitations (ONLS) test was performed at all - study visits, and is listed in the Statistical Analysis Plan as a secondary outcome measurement. This assessment is not listed in the protocol (b)(4) as part of any study visit.

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- The protocol (b)(4) says all data will be entered into a validated database, and at critical junctures, data will be locked and cleaned per established procedures (b)(4)

C. You did not monitor the progress of the clinical trial to ensure that the investigation was carried out consistently with the protocol, to prevent or mitigate sources of error in the conduct, collection, and reporting of critical study data, and to assure the safety of the subjects.

D. You did not ensure that the Principal Investigator and Study Director were trained to comply with Good Clinical Practices or to conduct the study in accordance with the protocol.

E. You did not obtain a signed investigator agreement from the Principal Investigator of the study.

F. You did not maintain records of shipment and disposition of study devices including:
- The name and address of the study staff and study site where devices were shipped
- The type and quantity of the devices shipped
- The dates the devices were shipped
- The serial number of the devices shipped

According to the batch records and discussions with you, - devices were manufactured for use in the study and were shipped to the clinical site. (b)(4) devices were not used and were returned to you at the end of the study.

G. The study data to be used to support the primary objective of the study, evaluating the effectiveness of (b)(4) (b)(4)

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- The protocol lists the primary efficacy endpoints as the change from *Baseline to* [redacted] for the following tests:
  Brief Pain Inventory (BPI)
  Pain Intensity Visual Analog Scale (VAS)
  Biochemical Parameters (FBS, PLBS, HbA1C)
  Neuropathic Pain Score Inventory (NPSI)
  Neuropathic Disability Score (NDS)
  Semmes-Weinstein 10g Monofilament Test
  Vibration Perception Threshold via biothesiometer (VPT)
  Pinprick Sensory Threshold (PPT)
  Patellar Reflex Response Test (Standard Patellar Hammer)

- The Statistical Analysis Plan lists the Pain Intensity Visual Analog Scale (VAS) from *Baseline to* [redacted] as the single test used to measure the primary outcome of the study.

  Biochemical parameters (FBS, PLBS, HbA1C) are listed as monitoring tests to be used for exploratory analysis.

  The Brief Pain Inventory (BPI), and Neuropathic Disability Score (NDS) are listed as only being used if the VAS score cannot be analyzed.

  The Vibration Perception Threshold via biothesiometer (VPT) is listed as a secondary outcome measurement.

  The Neuropathic Pain Score Inventory (NPSI), Semmes-Weinstein 10g Monofilament Test, Pinprick Sensory Threshold (PPT), and the Patellar Reflex Response Test (Standard Patellar Hammer) are not included in any part of the Statistical Analysis Plan.

SEE REVERSE OF THIS PAGE	Courtney N. Long, Investigator	Courtney N. Long -S Digitally signed by Courtney N. Long -S Date: 2022.12.15 12:55:27 +05'30'	DATE ISSUED 12/15/2022

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."