DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	11/14/2024-11/15/2024
	FEI NUMBER 1051088

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ilhan M. Bilgutay, President

FIRM NAME	STREET ADDRESS
Pace Tech, Inc.	515 S Martin Luther King Jr Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Clearwater, FL 33756-5607	Manufacturer

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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

The labels of the medical device(s) do not bear a unique device identifier (UDI) that meet the requirements of 801 Subpart B and 21 CFR 830.

Specifically, the PaceTech VitalMax and MiniPack patient cardiac monitors have not been labeled with Unique Device Identifiers (UDI).

OBSERVATION 2

Acceptance activities were not documented and maintained as part of the device history record.

Specifically, the acceptance activities performed upon receipt of critical components, throughout the assembly of the VitalMax and MiniPack patient cardiac monitors, and at final release of finished product are not documented and maintained in the Device History Record.

OBSERVATION 3

Procedures for corrective and preventive action have not been established.

Specifically, your firm has failed to establish a procedure for corrective and preventive action.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Suzanne M Healy, Consumer Safety Officer X Suzanne M Healy Consumer Safety Officer Signed By: Suzanne M. Healy -S Date Signed: 11-15-2024 13:23:50	11/15/2024

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EMPLOYEE(S) SIGNATURE

Suzanne M Healy, Consumer Safety Officer

X Suzanne M Healy
Consumer Safety Officer
Signed By: Suzanne M. Healy -S
Date Signed: 11-15-2024
13:23:50

DATE ISSUED
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Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Suzanne M Healy, Consumer Safety Officer X Suzanne M Healy Consumer Safety Officer Signed By: Suzanne M. Healy -S Date Signed: 11-15-2024 13:23:50	DATE ISSUED 11/15/2024

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."