DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg66-3513 Silver Spring, MD 20993-0002 (301)796-5490 Fax:(301)847-8136	8/8/2023-8/11/2023
	FEI NUMBER 3027402423

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Atul Verma, M.D., Principal Investigator

FIRM NAME	STREET ADDRESS
Atul Verma	581 Davis Drive, #206 , Southlake Regional Health Centre
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Newmarket, L3Y 8C3	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:

OBSERVATION 1

An investigation was not conducted according to the signed agreement.

Specifically, you failed to follow good clinical practice for record accuracy associated with Medtronic MDT 16027 clinical study in that source documentation was not accurately reflected in the electronic data base (EDC) for patients 003393-003, 003393-005, 003393-006, and 003393-016.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Stuart W Russell, Investigator - Dedicated BIMO Cadre	X Stuart W Russell Investigator - Dedicated BIMO Cadre Signed By: Stuart W. Russell -S Date Signed: 08-11-2023 11:48:54	8/11/2023

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE **INSPECTIONAL OBSERVATIONS** PAGE 1 of 1 PAGES

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."