DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
466 Fernandez Juncos Avenue San Juan, PR 00901-3223 (787)729-8500 Fax:(787)729-6809	4/23/2018-5/15/2018* FEI NUMBER 3004369318

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Felix M. Negron Yunque, Vice President of Operations

FIRM NAME	STREET ADDRESS
Medtronic Puerto Rico Operations Co.	Ceiba Norte Industrial Park, 50 Road 31 Km 24.4
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Juncos, PR 00777-3869	Medical Device 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 WE OBSERVED:

OBSERVATION 1

Procedures for corrective and preventive action have not been adequately established.

Specifically,

A. Corrective and preventive actions initiated by your firm have not been adequately implemented to ensure that distributed products comply with specifications necessary to prevent confirmed product failures which can adversely impact devices' safety and performance. For example:

CAPA 358912 was initiated on August 2017, as a result of confirmed electrical arcing on your implantable cardiac defibrillators. As documented in the CAPA, the reported and confirmed product failure was caused by (b) (4) of these devices. According to the CAPA investigation, the failure was caused (b) (4) , which consequently contributed (b) (4)

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(b) (4) . According to risks assessments documented under the CAPA, (b) (4) . Corrective actions implemented under the CAPA included (b) (4) . Nevertheless, no controls have been implemented as part of the CAPA to ensure the fulfillment of acceptable results (b) (4) , before impacted products are distributed.

B. Corrective and preventive actions are not implemented in a manner commensurate with the risk confirmed product failures represent upon finished products.

Internal risk assessment Rev. 1A, dated December, 2017, conducted by your firm as part of the investigation related to CAPA 358912, documented that "(b) (4) (b) (4) (b) (4) '. Nevertheless, (b) (4) (b) (4) (b) (4)

C. CAPA investigations do not adequately address the significance of confirmed device failures or controls in place to prevent its recurrence.

Internal risk assessment Rev. 1A, dated December 2017, conducted by your firm as part of the investigation related to CAPA 358912, determined that for (b) (4) (b) (4) . This was based on having an assigned detectability in the manufacturing process for the failure mode. According to established

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procedures, no further actions are needed for the resulting risk level. However, there (b) (4) (b) (4) . Furthermore, currently (b) (4) .

D. Corrective and preventive actions implemented to prevent the recurrence of reported problems did not reflect on related production procedures.

CAPA 358912 initiated on August 2017, documented that confirmed product failures of (b) (4) cardiac defibrillators (b) (4) . According to the CAPA investigation, the failure was caused by (b) (4) during production of these devices. Nevertheless, at the time of the inspection, manufacturing instructions contained on procedure "(b) (4) (b) (4)

E. Quality data sources are (b) (4) intended to identify the root cause of confirmed failures and to implement corrective actions to prevent its recurrence. For example:

Trending evaluations for (b) (4) (b) (4) your implantable cardiac defibrillators. The (b) (4) (b) (4) ". However, (b) (4) (b) (4) to corrective and preventive actions have been executed since the time the increasing failure rate was documented.

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OBSERVATION 2

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically,

Validation activities have not been conducted to ensure device specifications which cannot be fully verified by subsequent inspection are met. For example:

As documented on (b) (4) The confirmed arcing failures resulted in CAPA 358912, initiated on August 2017 and a subsequent field action. According to (b) (4) (b) (4) (b) (4) The (b) (4) (b) (4) (b) (4) . Nevertheless, manufacturing activities (b) (4) (b) (4) (b) (4) A total of approximately (b) (4) finished medical device units have been distributed by your firm since CAPA 358912 was initiated on August 2017.

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OBSERVATION 3
Procedures for acceptance activities have not been adequately established.

Specifically;

Acceptance activities have not been adequately implemented. For example:

A. Manufacturing procedures do not encompass acceptance criteria to ensure that documented evidence of results for (b) (4) your implantable cardiac defibrillators is confirmed before products are released. As per risks assessments documented on CAPA 358912, initiated on August 2017; (b) (4) . Corrective actions implemented under the CAPA included (b) (4) . The (b) (4) . Nevertheless, no controls have been (b) (4) .

B. (b) (4) . As documented on (b) (4) (b) (4) (b) (4) However, (b) (4) .

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OBSERVATION 4

Sampling plans are not based on valid statistical rationale.

Specifically,

(b) (4)
(b) (4) . For example:

A. (b) (4) . The report analyzed the potential non-conforming product from the samples tested against the (b) (4) . Nevertheless, (b) (4)

B. (b) (4) as a result of CAPA 358912 initiated on August 2017, (b) (4) . Nevertheless, there is no documented evidence of how this sample size is representative of the production volume manufactured in the same time frame. Since the time the CAPA was initiated, (b) (4)

OBSERVATION 5

Procedures to ensure equipment is routinely calibrated have not been adequately established.

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Specifically,

(b) (4) . For example:

As per procedure (b) (4)

(b) (4)

(b) (4) According to the (b) (4)

(b) (4)

Nevertheless, (b) (4) . The same was evidenced (b) (4) on these devices. According to (b) (4) .

OBSERVATION 6

(b) (4) have not been documented in the device history record.

Specifically,

Procedures for rework have not been adequately implemented.

According to procedure "(b) (4) (b) (4) implantable cardiac defibrillators (b) (4)

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(b) (4) Nevertheless, established manufacturing procedures were not implemented to ensure (b) (4)
(b) (4)

***DATES OF INSPECTION**

4/23/2018(Mon), 4/24/2018(Tue), 4/25/2018(Wed), 4/26/2018(Thu), 4/27/2018(Fri), 4/30/2018(Mon), 5/02/2018(Wed), 5/03/2018(Thu), 5/04/2018(Fri), 5/07/2018(Mon), 5/09/2018(Wed), 5/10/2018(Thu), 5/11/2018(Fri), 5/15/2018(Tue)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

Observation 5: Promised to correct

Observation 6: Promised to correct

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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."