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	10/1/2019-10/25/2019* FEI NUMBER 3004369318

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Felix M. Negron , Vice President - Puerto Rico 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.

A. Investigations concerning corrective and preventive actions did not include a thorough analysis of all contributing factors leading to identification of all underlying manufacturing processes and/or system concerning essential product specifications. Specifically;

The investigation of (b) (4) area related to Synchromed implantable sterile infusion pump devices and covered under CAPA 413664, (b) (4) for these implantable devices. The main objective of these qualifications/validations was to ensure the equipment would remain suitable for manufacturing before and after the established (b) (4) . (b) (4) was released at your facility in May 2018, and the (b) (4) were approved for use on July 23, 2018 and September 6, 2018, respectively. The August and September 2018 investigations of (b) (4) (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Laiza V Garcia, Investigator Dianiris C Ayala, Investigator Monica C Burgos Garcia, Investigator	X Laiza V Garcia Investigator Signed By: Laiza V. Garcia -S Date Signed: 10-25-2019 09:35:58	10/25/2019

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contaminated the final assembled devices and caused (b) (4) be above device established specifications.

Furthermore, the CAPA investigation concerning (b) (4)

Specifically, your firm did not evaluate (b) (4)

. Specifically, (b) (4)

The investigation did not consider (b) (4) , even when your firm had previously documented failures of (b) (4) and (b) (4) equipment related to a qualification/validation activity dated June 2018.

B.The implementation of proposed corrective and preventive actions related to confirmed lack of adequate purchasing controls as it relates to internal suppliers, has not been adequately established to be commensurate with the significance of precedent quality data sources. Specifically;

CAPA 396748, was initiated on 06/01/2018 to address findings that internal supplier controls procedures did not fully comply with purchasing controls and associated roles and responsibilities which were not clearly defined. Related root causes were identified as multiple functional areas executing controls and monitoring with no clear ownership of internal supplier management activities, and procedures being inadequate in defining a risk-based approach for establishing and implementing requirements, controls, and performance monitoring. The scope of the CAPA (b) (4)

(b) (4)

Nevertheless, the CAPA investigation did not consider other quality data

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sources such (b) (4), as well as their significance, which were attributed to components and/or services provided by your sister facilities. For example, quality holds provided during the inspection and documented since 2017, were initiated amongst other reasons as a result of non-conforming components, component mix-ups, missing tests, unclean material, and rejected products, which did not comply to specified requirements. Documented non-conformances related to your sister facilities included those initiated because of discrepancies in certificates of conformance, component mix-ups, and also non-conforming components. Furthermore, corrective actions did not begin to be implemented until 05/2019, 11 months after the CAPA was initiated. Moreover, corrective actions proposed under the CAPA are to be finalized on 2021, 3 years after the CAPA was initiated. Effectiveness of the corrective actions will be conducted after implementation has been completed.

OBSERVATION 2

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

Evaluation of confirmed failures on worst case conditions challenged during validation activities did not encompass rationale of the root causes attributed to the confirmed failures.

Specifically, your firm's Qualification of (b) (4)

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(b) (4)
(b) (4)
. Moreover, during and after the approval of the validations, your firm reported manufacturing failures (b) (4)

OBSERVATION 3

Process control procedures that describe any process controls necessary to ensure conformance to specifications have not been adequately established.

A. Production and process control procedures to ensure that devices conform to required specifications after (b) (4) have not been adequately established. Specifically;

Procedure "MF_0084 Diabetes NGP Master Manufacturing Procedure", in turn references established procedures to manage the salvage of components which can be (b) (4) finished units of your NGP insulin infusion pumps. The (b) (4) defined on procedure "10193394DOC (b) (4) Description/NGP Pump Disassembly". The process of (b) (4) has been conducted at your firm since first implemented on 2015. The (b) (4) . Nevertheless, at the time the (b) (4) was initiated, no testing was implemented in order to be indicative of potential impact on the useful life of components, or any potential impact to finished products after (b) (4) . Furthermore, the related testing was not implemented until 04/2019, at the time the use of (b) (4)

B. Procedures to determine the significance of confirmed and potential non-conformities, as it relates to quality data sources have not been adequately established. Specifically;

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QH000930 was issued on 7/13/2018 to bound product processed during the qualification/validation of (b) (4) . The risk associated with this (b) (4) . QH000930 was (b) (4) . QH000975 issued on 9/21/18, was created t (b) (4) , product M960126A001 and M960126A002. The risk associated with this (b) (4)

Nevertheless, (b) (4) .

OBSERVATION 4

Procedures that define the responsibility for review and the authority for the disposition of nonconforming product have not been adequately established.

A.Procedures to manage potential and confirmed non-conformities have not been adequately established, to ensure that the potential impact of confirmed problems can be adequately evaluated after related corrective actions intended to prevent recurrence are implemented.

Specifically, the impact of confirmed problems is evaluated and defined at the time non-conformities are documented, regardless of the lack of established failure modes, related controls, and subsequent implementation of corrective and preventive actions intended to prevent recurrence. CAPA 399193 was initiated on 06/18/2018, in order to investigate the events surrounding the (b) (4) of your NGP insulin infusion pumps. Reportedly, (b) (4) QH000911, dated 05/18/2018. Nonconformities concerning the rejected device units and related components included; (b) (4)

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(b) (4) . When initiated and evaluated, (b) (4) According to (b) (4)

The resulting risk level was determined from the PFMEA applicable to affected product and documented on (b) (4) . Nevertheless, as documented under the (b) (4) for the reported event, (b) (4) The (b) (4) was partially released on 06/2018 and 09/2018. Nevertheless, the CAPA investigation intended to identify related root causes for the confirmed (b) (4) , and the respective PFMEA was revised on (b) (4) Corrective actions intended to prevent the confirmed component mix-up events were implemented and finalized on (b) (4) . Effectiveness of corrective actions implemented under the CAPA were finalized on (b) (4) . As per section 1.2 of procedure "MPR_PPC_WI_009535 (b) (4) " (b) (4) PFMEA's. Nonetheless, there are no provisions included as part of the procedure (b) (4)

B.Procedures for managing non-conformities, (b) (4) have not been adequately established to define a permissible amount of (b) (4) , before nonconformities are investigated.

Specifically, procedure "MPR_PPC_WI_009055 (b) (4) " establishes instructions to manage non-conformities. As per the procedure there are potential dispositions for non-

conforming product and related non-conformities. Nevertheless, the procedure lacks specificity as to a (b) (4), as it relates to the significance of reported non-conformities.

C. Procedures for the control and disposition of non-conforming and/or potentially non-conforming product have not been adequately implemented to ensure that (b) (4)

Specifically, procedure "MPR_PPC_WI_009535 (b) (4) establishes (b) (4) used at your firm to manage and prevent the further processing of potential nonconforming product, sub-assembly and/or components. This procedure establishes specific instructions for the identification of (b) (4). Your firm failed to adequately establish this procedure in that (b) (4) Furthermore, discrepant information was documented for the conditions for release and release dates. For example:

i (b) (4) QH000930 was created on 07/13/18 to contain product until the validation for (b) (4). Still, (b) (4)

ii (b) (4) As per QH000930.14, (b) (4) was released to the manufacturing area on 09/06/18 with reason for (b) (4) on (b) (4). This (b) (4) was also listed as released on 09/07/18 under QH000930.18 indicating the reason for release to be the validation activities for JUN-0161 were completed.

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iii. (b) (4) HG2S9UA was also processed on equipment (b) (4) . As per QH000930.14, this subassembly was released to the manufacturing area on 09/06/18 with reason for release (b) (4) This (b) (4) under QH000930.18 indicating the reason for release to be the validation activities for JUN-0161 were completed. As (b) (4)

iv. DHRs do not consistently document product disposition activities in relationship to respective quality holds.

***DATES OF INSPECTION**

10/01/2019(Tue), 10/02/2019(Wed), 10/03/2019(Thu), 10/04/2019(Fri), 10/08/2019(Tue), 10/09/2019(Wed), 10/10/2019(Thu), 10/11/2019(Fri), 10/15/2019(Tue), 10/18/2019(Fri), 10/21/2019(Mon), 10/25/2019(Fri)

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Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

Observation 4:

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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."