**Class 2 Device Recall**  
**InterStim(TM) System**

**Date Initiated by Firm**: May 15, 2019  
**Date Posted**: June 07, 2019  
**Recall Status**: Open, Classified  
**Recall Number**: Z-1774-2019  
**Recall Event ID**: 826263  
**PMA Number**: P970004S268, P080025S163  
**Product Classification**: Stimulator, electrical, implantable, for incontinence - Product Code EZW  
**Product**: InterStim(TM) System, Model Numbers:  
a) TH90G01  
b) TH90GFA  
c) TH90G02  
d) TH90G03  

**Product Usage**:  
The Medtronic Model A510 Clinician application (app) is intended for use with the HH90 Handset and TM90 Communicator to program, adjust, and troubleshoot the Medtronic Models 3023 and 3058 InterStim® neurostimulators for sacral neuromodulation therapy. The clinician uses the Clinician app to program settings for the patient. The A510 Clinician app, HH90 Handset, TM90 Communicator along with the A520 Patient app are only sold as a kit (TH90).  

**Code Information**:  
Model Numbers/UDI:  
a) TH90G01/00763000058005  
b) TH90GFA/00763000187231  
c) TH90G02/00763000192259, 00763000192266, 00763000192273, 00763000192280, 00763000192297, 00763000192303, 00763000192310  
d) TH90G03/00763000192310  
ALL LOT/SERIAL NUMBERS
Recalling Firm/Manufacturer
Medtronic Neuromodulation
7000 Central Ave Ne
Minneapolis MN 55432-3568

For Additional Information Contact
Medtronic Technical Services
800-707-0933

Manufacturer Reason for Recall
There is a potential for an unexpected increase in stimulation during InterStim programming with the A10 Clinician Application (on Medtronic’s smart programmer).

FDA Determined Cause
Software design

Action
Medtronic sent an Urgent Medical Device Safety Notification letter dated May 2019, to US Physicians and European physician. The notifications were delivered by mail, personal delivery by Medtronic Representatives, fax, or equivalent method. A confirmation form will be used to document receipt and understanding of the notification, and a minimum three attempts will be made to obtain confirmation from non-responding physicians that the notification has been received and understood.

Quantity in Commerce
13979 units

Distribution
Worldwide Distribution - US Nationwide & PR, and Germany, Switzerland, Italy, Spain, France, UK, Norway, Denmark, Finland, Netherlands

Total Product Life Cycle
TPLC Device Report

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1 A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls.

2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

3 The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

PMA Database
PMAs with Product Code = EZW and Original Applicant = MEDTRONIC NEUROMODULATION
Class 2 Device Recall InterStim(TM) System

10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)

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19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=82626
24. /scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P970004S268
25. /scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P080025S163
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=EZW
27. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=EZW
28. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=EZW
29. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
