Class 2 Device Recall InterStim(TM) System

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Date Initiated by Firm	May 15, 2019
Date Posted	June 07, 2019
Recall Status[1]	Open[3], Classified
Recall Number	Z-1774-2019
Recall Event ID	82626[23]
PMA Number	P970004S268[24] P080025S163[25]
Product Classification	Stimulator, electrical, implantable, for incontinence[26] - **Product Code** EZW[27]
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 [2]	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[28]

[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[29].

[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[30]

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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
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
30. /scripts/cdrh/cfdocs/cfPMA/pma.cfm?start_search=1&productcode=EZW&applicant=MEDTRONIC%20NEUROMODULATION

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20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=82626
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26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=EZW
27. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=EZW
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29. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm

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