Class 2 Device Recall Activa PC

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Date Posted	August 18, 2014
Recall Status[1]	Open
Recall Number	Z-2259-2014
Recall Event ID	68935[23]
Product	Medtronic, Activa PC, Model 37601, Method of Sterilization: Ethylene Oxide, Single Use Only, Rx Only. The Activa® PC neurostimulator is a dual-channel device capable of delivering bilateral stimulation. Activa PC contains a non-rechargeable battery and microelectronic circuitry to deliver a controlled electrical pulse to precisely targeted areas of the brain. The device is typically implanted subcutaneously near the clavicle, connected to an extension and leads, which are implanted in the brain.
Code Information	Serial numbers: NKM724776H, NKM724782H, NKM724785H, NKM724790H, NKM724802H, NKM724843H.
Recalling Firm/ Manufacturer	Medtronic Neuromodulation 7000 Central Ave Ne Minneapolis, Minnesota 55432-3568
For Additional Information Contact	Medtronic Representative 800-633-8766
Manufacturer Reason for Recall	Medtronic is recalling six Activa PC (model 37601) Implantable Neurostimulators due to the potential for a damaged electrical component during manufacturing.
Action	The firm, Medtronic, notified their Consignees on 07/14/2014 via telephone of the recall. Medtronic representative used telephone script to convey the information. The script was directed to Risk Management or Inventory Management. The caller was to inform consignees of the problem and product being recalled. Advised consignees to quarantine the product and provided the Medtronic Device Removal Reply Form to the consignees via e-mail or Fax. The Reply Form included contact information which was to call 1-800-633-8766 in case they needed to contact a Medtronic representative. The completed form is to be faxed back to 1-800-897-3899 or e-mail a PDF to neuro.quality@medtronic.com. If you have any questions, call 763-526-1294.
Quantity in Commerce	6
Distribution	Distributed in the states of: MA, NC, OH, and TX.

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[24]

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